# UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

04-1323, -1487

ARTHROCARE CORPORATION,

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

# ORDER

# United States Court of Appeals for the Federal Circuit



ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the APPELLEE,* and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on July 12, 2005.

FOR THE COURT,

Jan Horbaly
Clerk

Dated: July 5, 2005



cc: Ruffin B. Cordell
Jared Bobrow, Vicki Margolis

ARTHROCARE V SMITH & NEPHEW, 04-1323, -1487
(DCT - 01-CV-504)

* Filed by ArthroCare Corporation.

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* Note: Pursuant to Fed. Cir. R. 47.6, this order is not *
* citable as precedent. It is a public record. *
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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| ARTHROCARE CORPORATION, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 01-504-SLR |
| | ) | |
| SMITH & NEPHEW, INC., | ) | |
| | ) | |
| Defendant. | ) | |

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Jack B. Blumenfeld, Esquire, Karen Jacobs Louden, Esquire and James W. Parrett, Jr., Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Matthew D. Powers, Esquire, Jared Bobrow, Esquire and Perry Clark, Esquire of Weil, Gotshal & Manges LLP, Redwood Shores, California.

William J. Marsden, Jr., Esquire and Keith A. Walter, Jr., Esquire of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Mark J. Hebert, Esquire and Kurtis D. MacFerrin, Esquire of Fish & Richardson P.C., Boston, Massachusetts.

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**MEMORANDUM OPINION**

Dated: March 10, 2004
Wilmington, Delaware

ROBINSON, Chief Judge

## I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful direct, contributory, and inducing infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent"). (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (Id.) Smith & Nephew also asserted counterclaims for a declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended their answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219)

ArthroCare is organized under the laws of the State of Delaware with its principal place of business in California. (D.I. 1 at ¶2) Smith & Nephew is also organized under the laws of State of Delaware with its principal place of business in

Massachusetts. (Id. at ¶3) The court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

The court separated the issues raised by the parties into two phases, the first phase to include the issues of infringement, validity, and inequitable conduct and the second phase to include the issues of damages, willfulness, and antitrust counterclaims. From April 30, 2003 through May 9, 2003, the parties tried the issues of infringement and invalidity before a jury. The court ruled on May 12, 2003 that the parties could submit their inequitable conduct cases on the briefs limited to the record created at trial. (See D.I. 418 at 1071-02) Currently before the court are the parties' post-trial motions on the issues of infringement, invalidity, and inequitable conduct.[1] (D.I. 424, 427, 432, 437, 455, 458)

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[1]Smith & Nephew challenges every decision made by the jury in rendering its verdict and numerous evidentiary decisions rendered by the court during the trial.

Smith & Nephew filed a motion to modify the protective order to permit key Smith & Nephew business personnel to view specific terms of Arthrocare's settlement agreement with Ethicon in an attempt to facilitate settlement discussions between the parties. (D.I. 432) Because there are no active settlement discussions currently ongoing, the court denies this motion as moot.

Smith & Nephew also filed a motion for judgment as a matter of law on the issues of (1) infringement under the doctrine of equivalents; (2) infringement of claim 54 of the '882 patent by non-suction models of the Saphyre probe; and (3) direct infringement of the '592 and '882 patents. (See D.I. 459 at 5, 6, and 19) None of these issues were presented to the jury. Likewise, neither the jury instructions nor the special verdict form asked the jury to decide these issues. Accordingly, the court finds that judgment as a matter of law is improper under the federal rules and will not entertain these motions.

## II. BACKGROUND

### A. Electrosurgery In General

The patents in suit generally relate to electrosurgery and to surgical devices and methods that employ high frequency voltage to cut and ablate tissue. These devices are of either a monopolar or a bipolar nature. A monopolar device, as the name suggests, consists of only a single electrode. It directs an electric current from the exposed or active electrode through a patient's body to a return electrode externally attached to the patient's body. In contrast, a bipolar device consists of two electrodes. An active electrode in contact with the patient's tissue transmits an electric current through the patient's tissue to a return electrode also in contact with the patient's tissue. When using either type of device, the target region must be treated with isotonic saline to maintain an isotonic environment around the tissue and to keep the area in clear view.

Electrosurgical techniques are advantageous because they reduce patient bleeding and the trauma associated with operations involving cutting. At the same time, a diverse range of risks may be implicated. With monopolar devices, electric current may flow in undefined paths through a patient's body. Also, high voltages typically must be applied to generate a current suitable for cutting or ablation using either monopolar or bipolar

devices. Such high voltage may damage or destroy surrounding tissue.

**B. The Patents In Suit**

The patents in suit involve improvements over the monopolar and bipolar devices of the prior art. Specifically, the '536 patent claims an electrosurgical system comprising an electrosurgical probe, a return electrode, and a fluid delivery element. The '592 and '882 patents, in turn, claim methods of using the system disclosed in the '536 patent to apply electrical energy adjacent to the target tissue without submerging the target tissue in an electrically conducting irrigant. Each patent will be considered in further detail as relevant to the parties' post-trial motions.

**1. The '536 Patent**

The '536 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 18, 1996. The '536 patent traces priority to the now abandoned U.S. Application No. 817,575. It was granted with sixty-four claims on December 16, 1997. On December 23, 1999, a third party filed a request for an ex parte reexamination based solely upon prior art. The United States Patent and Trademark Office ("PTO") granted this request

and, after reexam, issued a "Notice of Intent to Issue an Ex Parte Reexamination Certificate" as to all original claims.

Claims 46, 47, and 56 are presently asserted and are apparatus type claims. Claims 46 and 56 depend from claim 45. Claim 47 depends from claim 46. These claims read as follows:

> 45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:
> a high frequency power supply;
> an electrsurgical probe comprising a shaft having a proximal end and a distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;
> a return electrode electrically coupled to the electrosurgical power supply; and
> an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.
>
> 46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.
>
> 47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.
>
> 56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

('536 patent, col. 18 at ll. 13-36; col. 19 at ll. 11-15)

The court construed disputed terms of the '536 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The term "electrosurgical system" shall be given its "ordinary definition" and construed to mean "an assemblage or combination of things or parts forming a unitary whole."

2. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."

3. The term "connector" shall be construed to mean "a structure that electrically links the electrode terminal to the high frequency power supply."

4. The phrases "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" shall be construed to mean that the return electrode is not to contact the body at all during the performance of the claimed method.[2]

5. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

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[2]The court supplemented this construction in its jury instructions with the following addition: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

### 2. The '882 Patent

The '882 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 22, 1995 and traces priority to the same original application as the '536 patent, namely U.S. Application No. 817,575. The '882 patent was granted with fifty-six claims on December 16, 1997. Claims 13, 17, and 54 are presently asserted. All are method type claims. Claims 13 and 17 depend from claim 1 and claim 54 depends from both claim 1 and claim 28. These claims recite:

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode, electrically coupled to a high frequency voltage source;
positioning the active electrode in close proximity to the target site in the presence of an electrically conducting fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.

28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, col. 24 at ll. 5-18; 54-56, 64-65; col. 25 at ll. 38-51; col. 28 at ll. 9-10)

Pursuant to multiple certificates of correction granted after the '882 patent originally issued, the language recited in several claims was corrected. Of interest to the parties' post-trial motions, claim 1 was corrected on April 7, 1998. Claim 54 was corrected on May 2, 1998. For sake of clarity, the corrected language is shown below in bold with the original language in parentheses.

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode **terminal** in close proximity to the target site in the presence of an electrically conducting [terminal] **fluid**; and
applying a high frequency voltage between the electrode terminal and the return electrode,

the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

54. The method of claims [1 and 28] **23 or 48** further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, Certificates of Correction dated August 25, 1998, April 7, 1998, and May 2, 2001)(emphasis added)

### 3. The '592 Patent

The '592 patent, entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," was issued on May 1, 2001 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on July 27, 1998 and traces priority to the '882 patent. Specifically, the '592 patent is a division of U.S. Patent No. 5,871,469, which is a division of the '882 patent. The '592 patent was granted with forty-three claims on May 1, 2001. Claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 are presently asserted and are all method type claims. Claims 3, 4, 11, and 21 depend from claim 1. Claim 26, 27, 32, and 42 depend from claim 23. These claims read as follows:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:
positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;
positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate

a current flow path between the electrode terminal and the return electrode; and

applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

3. The method of claim 1 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.

4. The method of claim 1 further comprising delivering the electrically conductive fluid to the target site.

11. The method of claim 1 wherein the electrically conductive fluid comprises isotonic saline.

21. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:

contacting an active electrode with the body structure in the presence of an electrically conductive fluid;

spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and

applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.

26. The method of claim 23 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path

between the active electrode and the return electrode.

27. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.

32. The method of claim 23 wherein the electrically conductive fluid comprises isotonic saline.

42. The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

('592 patent, col. 24 at ll. 6-21; 36-32; 64-65; col. 25 at ll. 36-37, 43-54, 61-67; col. 26 at ll. 20-21, 59-60)

The court construed disputed terms of the '592 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The phrase "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" means that the return electrode is not to contact the body at all during the performance of the claimed method.[3]

2. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

3. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."

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[3]The court supplemented this construction in its jury instructions. The court added the following: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

(D.I. 353)

**C. The Accused Products**

Smith & Nephew presently manufactures and sells the Saphyre bipolar ablation probe ("Saphyre") and the ElectroBlade Resector ("ElectroBlade") for use in arthroscopic procedures. These products entered the market in 2002. It also previously manufactured and sold the Dyonics Control RF System ("Control RF") for use in arthroscopic procedures, but discontinued this product from the market in early 2002. (D.I. 436 at 3)

The Saphyre product consists of a stainless steel shaft with a plastic handle and a single large area active electrode at the far or "distal" end of the "shaft." (D.I. 400 at 3) The inner and outer surfaces of the Saphyre shaft are covered with an insulating coating, except at the distal tip where the active electrode is located. (Id.) A single return electrode clip is attached on top of this insulated shaft. (Id.) The return electrode and insulated shaft are covered with another insulating layer, except for a window located over the return electrode clip near the distal end of the shaft. (Id.) The Saphyre probe is connected to the Smith & Nephew Vulcan Generator. (Id. at 4)

The ElectroBlade probe consists of a stainless steel inner tube (i.e., inner blade) and a hollow stainless steel shaft (i.e., outer blade). (Id.) The inner blade slides into the shaft hollow and includes an opening near its distal end. The

inner blade rotates within the shaft when connected to a motor drive unit. (Id.) When it passes the edge of the opening in the shaft during rotation, a shearing action results. (Id. at 5) This shearing action serves to resect, or cut, target tissue. In addition to resecting tissue, the inner blade also acts as the active electrode when coagulation power is applied to the probe. (Id.) The return electrode is another hollow, stainless steel tube that runs from a point close to the opening in the shaft to a point in the handle. (Id.) The return electrode is covered with an insulating layer, except for an exposed section near the distal end of the shaft. The ElectroBlade probe does not contain a fluid delivery system. Instead, a separate instrument delivers fluid to the target tissue during an arthroscopic procedure. (Id. at 4) The ElectroBlade probe is connected to the Valleylab Force FX Generator. (Id. at 5)

Before being discontinued, the Control RF probe consisted of a stainless steel shaft in a plastic handle with a single active electrode at the far end. (Id. at 6) A return electrode was located near the active electrode at the far end of the shaft. The majority of the shaft was covered with an insulating material, except in the region of the active and return electrodes. (Id.) The Control RF probe did not contain a fluid delivery system; instead, a separate instrument pumped fluid during an arthroscopic surgery to the target tissue. (Id.) The

Control RF probe was connected to a Valleylab Force FX Generator via a Dyonics Control RF Generator Adaptor. (Id.)

**D. The Alleged Prior Art**

Throughout the course of the trial, Smith & Nephew introduced numerous documents in an attempt to establish that the patents in suit were invalid in light of prior art references.[4] These references include four patents and two journal articles as follows: (1) U.S. Patent No. 4,116,198 (the "'198 patent"); (2) U.S. Patent No. 4,381,007 (the "'007 patent"); (3) U.S. Patent No. 4,674,499 (the "'499 patent"); (4) U.S. Patent No. 5,122,138 (the "'138 patent"); (5) "Vaporization of Atherosclerotic Plaques by Spark Erosion," 5 Journal of the American College of Cardiology, No. 6 at 1382-6 (1985) written by Cornelis J. Slager, et. al. (the "Slager article"); and (6) "Uber ein Instrument zur leckstromfreien transurethralen Resektion," (translated as "An Instrument for Transurethral Resection Without Leakage of Currents"), 24 Acta Medico Technica, No. 4 at 129-134 (1976) written by Von E. Elsasser and Eberhard. Roos (the "Elsasser/Roos article"). The '007 and '499 patents were cited to the PTO during the prosecution of the '536 and '882 patents. (See '536 patent cover; '882 patent cover) The Elsasser/Roos article was also cited during the prosecution of the '536 patent, and the

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[4]The parties did not dispute that the documents introduced at trial by Smith & Nephew qualified as prior art in that they were available prior to the filing dates of the patents in suit.

'198 patent was cited during the reexamination of the '536 patent. (See '198 patent cover; '198 patent reexamination certificate)

The '198 patent, entitled "Electro-Surgical Device," is the most contentious item of prior art raised in the litigation at bar. Eberhard Roos is named as the sole inventor on this patent. In general, it relates to a bipolar electrosurgical device that may be passed through an endoscope. The device consists of a treatment electrode, a neutral electrode, a cable means to connect the treatment electrode to one pole of a high-frequency generator, another means for connecting the neutral electrode to the other pole of the high-frequency generator, and a channel for directing washing liquid to the treatment site. ('198 patent, col. 7 at ll. 45-61) The '198 invention is particularly directed toward electrosurgical operations on the filled bladder. (Id., col. 1 at ll. 18-21) Claim 1 of this patent recites:

> 1. In combination, an endoscope having an endoscope body of substantially tubular shape, an electro-surgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, **a space being**

**formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.**

(Id., col. 7 at ll. 45-62)(emphasis added)

The '007 patent is entitled, "Multipolar Corneal-Shaping Electrode with Flexible Removable Skirt," and names James D. Doss as the sole inventor. This patent is directed toward a multipolar probe that employs radiofrequency electrical current to heat and thereby induce reshaping of the cornea in mammals. ('007 patent, col. 1 at ll. 10-13) The probe employs a plurality of electrode means that may be connected to the terminal of a radio-frequency source. (Id., col. 6 at ll. 60-61)

The '499 patent is entitled, "Coaxial Bipolar Probe," and names David S.C. Pao as the scle inventor. It discloses an electrosurgical bipolar electrode probe for use in ophthalmic, electrocautery, and electrocoagulation operations. ('499 patent, col. 1 at ll. 15-18)

The '138 patent is entitled, "Tissue Vaporizing Accessory and Method for an Endoscope," and names Kim H. Manwaring as the sole inventor. This patent is directed toward radio frequency energized endoscopic tissue dissection, vaporization, and coagulation devices designed for use in conjunction with an endoscope. ('138 patent, col. 1 at ll. 7-9; col. 2 at ll. 5-8) These devices may utilize a monopolar RF generator.

The Elsasser/Roos article essentially describes using one of the bipolar electrosurgery devices described in the '198 patent in thirty-two surgeries. In the summary section, this article states that "[t]he high-frequency current . . . flows directly from the active cutting electrode, **through the tissue to be cut and the irrigation liquid**, to the annular neutral electrode at the proximal end of the resectoscope shaft." (DTX 59-B at 7)(emphasis added) The Slager article describes the in vitro vaporization of fibrous and lipid plaques from segments of atherosclerotic human aortas using an electrical spark generator. (DTX 65)

**E. The Arthrocare Corp. v. Ethicon, Inc. Decision**

Arthrocare filed suit against Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. in the Northern District of California on February 13, 1998, alleging infringement of eight claims in four patents. (Arthrocare Corp. v. Ethicon, Inc., No. C-98-0609 WHO (N.D. Cal. Dec. 1, 1998); D.I. 321, ex. A at 1) The claims at issue included: (1) claims 40 and 44 of U.S. Patent No. 5,697,909 (the "'909 patent"); (2) claim 45 of the '536 patent; (3) claim 101 of U.S. Patent No. 5,697, 281 (the "'281 patent"); and (4) claims 1, 26, 28, and 32 of the '882 patent. (Id. at 2) The case was assigned to Senior Judge William H. Orrick.

On March 10, 1998, Arthrocare moved for a preliminary injunction against Ethicon and Mitek to enjoin the two from making, using, importing, selling, or offering for sale an electrosurgery system marketed and sold under the VAPR System name. (Id.) Judge Orrick issued a memorandum decision on December 1, 1998 denying Arthrocare's preliminary injunction motion. (Id. at 33) Judge Orrick found substantial questions as to whether: (1) claims 40 and 44 of the '909 patent and claims 26 and 28 of the '882 patent are invalid for obviousness in light of the '198 patent and Elsasser/Roos article; (2) claim 45 of the '536 patent and claim 101 of the '281 patent are invalid for anticipation and obviousness in light of the '198 patent and Elsasser/Roos article; and (3) claims 1 and 32 of the '882 patent are invalid for lack of enablement. (Id.) The parties settled the litigation in June 1999 prior to trial.

**F. Procedural History**

In March 2003, the parties filed multiple motions for partial summary judgment. The court heard oral argument regarding these motions on April 1, 2003 and issued a memorandum opinion and order on April 9, 2003. (D.I. 352) The court denied Arthrocare's motions for partial summary judgment of infringement of the asserted claims of the '882 patent and claim 1 of the '592 patent, denied Smith & Nephew's motion for summary judgment of noninfringement of the asserted claims of the '882, '592, and

'536 patents, denied Arthrocare's motion for partial summary judgment that the patents in suit are not invalid due to obviousness based on an on-sale bar or public use, denied Smith & Nephew's motion for summary judgment of invalidity based upon prior art, and denied Smith & Nephew's motion for partial summary judgment of nonenablement, indefiniteness, and lack of written description. (Id.)

During the April 1, 2003 oral argument, the court also heard the parties' positions with respect to the disputed claim language of the patents in suit in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). The court issued a claim construction memorandum order on April 9, 2003. (D.I. 353)

**G. The Trial**

On April 30, 2003 through May 12, 2003, the parties tried their claims to a jury. The jury found by a preponderance of the evidence that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of claims 46, 47, and 56 of the '536 patent with its Saphyre, ElectroBlade, and Control RF products. (D.I. 405) The jury also found by clear and convincing evidence that the certificate of correction for claim 1 of the '882 patent was not invalid and by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 13, 17, and 54 of the

'882 patent with its Saphyre, Saphyre with Suction, and Control RF products. (Id.) In addition, the jury found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent with its Saphyre, ElectroBlade, and Control RF products.[5] (Id.) The jury further found that Smith & Nephew did not prove by clear and convincing evidence that the patents in suit are invalid due to anticipation or that claims 13, 17, and 54 of the '882 patent are invalid for lack of enablement. (Id.) The court entered final judgment on June 20, 2003 based upon the jury's verdict. (D.I. 452)

## III. STANDARD OF REVIEW

### A. Motion for Judgment as a Matter of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial under Federal Rule of Civil Procedure 50(b), the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.'" Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)

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[5]The jury was not asked to decide whether Smith & Nephew contributed to the infringement or induced the infringement of claims 21 and 42 of the '592 patent with its Saphyre or ElectroBlade products.

(quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." Id. In summary, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

**B. Motion for a New Trial**

The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. See Allied Chem. Corp. v. Darflon, Inc., 449 U.S. 33, 36 (1980).

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

> A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

New trial are commonly granted in the following situations: (1) where the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) where newly-discovered evidence surfaces that would likely alter the outcome of the trial; (3) where improper conduct by an attorney or the court unfairly influenced the verdict; or (4) where the jury's verdict was facially inconsistent. See Zarow-Smith v. N.J. Transit Rail Operations, 953 F. Supp. 581, 584 (D. N.J. 1997) (citations omitted). The court, however, must proceed cautiously and not substitute its own judgment of the facts and assessment of the witnesses' credibility for the jury's independent evaluation. Nevertheless,

> [w]here a trial is long and complicated and deals with a subject matter not lying within the ordinary knowledge of jurors a verdict should be scrutinized more closely by the trial judge than is necessary where the litigation deals with material which is familiar and simple, the evidence relating to ordinary commercial practices. An example of subject matter unfamiliar to a layman would be a case requiring a jury to pass upon the nature of an alleged newly discovered organic compound in an infringement action.

Lind v. Schenley Indus. Inc., 278 F.2d 79, 90-91 (3d Cir. 1960).

## IV. DISCUSSION

### A. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Direct Infringement Grounds[6]

#### 1. The Legal Standard for Direct Infringement

A patent is directly infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a) (2002). A court should employ a two-step analysis in making a direct infringement determination. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. See id. Construction of the claims is a question of law subject to de novo review. See Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). The trier of fact must then compare the properly construed claims with the accused infringing product. See id. This second step is a question of fact. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). Direct infringement occurs where each limitation of

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[6]When motioning the court for a new trial under Fed. R. Civ. P. 59, Smith & Nephew appears to also move for a new trial under Fed. R. Civ. P. 50(b). Smith & Nephew premises this motion on the same grounds raised in its motion for judgment as a matter of law under Fed. R. Civ. P. 50(b). (See D.I. 456 at 33-34). The court, therefore, shall consider its Rule 50(b) motion for judgment as a matter of law as including an alternative motion for a new trial.

at least one claim of the patent is found exactly in the alleged infringer's product. See Pancuit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987). The patent owner has the burden of proving direct infringement and must meet its burden by a preponderance of the evidence. See SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

**2. The '536 Patent**

Smith & Nephew renews its motion for judgment as a matter of law that its accused products cannot directly infringe independent claim 45 or dependent claims 46, 47, or 56 of the '536 patent because the probes covered by the '536 patent must deliver fluid to the target site in light of the court's claim construction for the term "electrosurgical system." Smith & Nephew asserts that the probes used in its Saphyre, Control RF, and ElectroBlade products do not introduce such a fluid supply, even though they are used in the presence of electrically conducting fluid. To this end, Smith & Nephew explains that fluid is introduced to the target site by a separate piece of medical equipment like an IV bag or an Intelijet pump and that the separate equipment is not part of the "electrosurgical system." (D.I. 415 at 976, 1014) Smith & Nephew alleges that Arthrocare's expert, Dr. Nahum Goldberg, improperly ignored the requirement that an electrically conducting fluid supply be part

of the claimed system in his testimony at trial. (See D.I. 411 at 398-99) Accordingly, Smith & Nephew maintains that its products fall outside the scope of the asserted claims in the '536 patent.

The court disagrees. A jury reasonably may have discounted all testimony presented by Smith & Nephew with respect to direct infringement of the '536 patent after finding Smith & Nephew's use of the term "electrosurgical system" inconsistent with the court's claim construction. The court construed this term to mean "an assemblage or combination of things or parts forming a unitary whole." The court did not require that all elements physically interconnect as implied by Smith & Nephew. Following the court's construction, the jury likely understood that fluid may be delivered from any source (e.g., the probe itself, an IV bag, or an Intelijet pump) and still permit formation of an "electrosurgical system."

Additionally, there is ample evidence in the record upon which a jury reasonably could have concluded that the accused products meet all limitations of the asserted claims. Dr. Goldberg testified that the accused devices will only function in the presence of electrically conducting fluid. (See id. at 398-99, 405, 412) Smith & Nephew's own expert, Dr. Kenneth Taylor, also testified that the accused devices require, and will not work without, electrically conducting fluid. (See D.I. 416 at

1453-54) Dr. Taylor likewise admitted that a probe is not required to deliver fluid for the probe and fluid supply to be considered an "electrosurgical system." (See id. at 1413-16) Moreover, Dr. Taylor explained the components described in the Slager reference comprised an electrosurgical system, even though fluid was not delivered through the probe. (See id. at 1414)

Besides direct witness testimony, the jury viewed multiple video clips of the accused products in operation during "normal procedure." (See PX 105, DTX 315, DTX 316, DTX 897) In all clips, the target sites were submerged under saline fluid. (Id.) The jury further saw product literature from Smith & Nephew, namely the ElectroBlade "Instruction for Use" guide, which described the use of the ElectroBlade in conjunction with the Intelijet pump and referred to this assembly as the "Recommended System Configuration." (PX 189 at 3) On the basis of this evidence, a reasonable jury could conclude that the Saphyre, Control RF, and ElectroBlade probes form an "electrosurgical system" as required by the '536 claims and, as such, infringe the '536 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '536 patent is not infringed by the accused products.

Concerning a new trial, the verdict is not against the weight of the evidence and no miscarriage of justice will result if the jury's verdict stands. Smith & Nephew did not present

evidence that so overwhelmingly favors its position that the jury clearly erred in finding that the accused products directly infringe the '536 patent. In addition, the court finds that none of the other reasons for granting a new trial, such as the discovery of new evidence or improper attorney conduct, exist under the facts at bar. Thus, the court denies Smith & Nephew's motion for a new trial as to literal infringement of the '536 patent.

### B. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, Based Upon the Validity of the Certificate of Correction for the '882 Patent

Smith & Nephew argues that its Saphyre, ElectroBlade, and Control RF probes would not directly infringe the '882 patent but for the certificate of correction that broadened the number of electrodes recited in application claim 23, which became patent claim 1, from four electrodes (i.e., an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal) to two electrodes (i.e., an electrode terminal and a return electrode). In other words, Smith & Nephew does not contest that its Saphyre, Control RF, and ElectroBlade products directly infringe the asserted claims of the '882 patent as corrected by the certificate of correction because its accused probes have only two electrodes as recited by the corrected

claims.[7] (See D.I. 415 at 1110-1112) Rather, Smith & Nephew argues that the certificate of correction is invalid. In this regard, Smith & Nephew asserts that it was not obtained to correct a mistake, but only to broaden the claims to advance its lawsuit against Ethicon. Additionally, Smith & Nephew argues that, even if the certificate was filed to correct obvious errors, it was not manifest how such corrections should have been made.

The court disagrees. The record is replete with evidence upon which a jury reasonably could have found that the certificate of correction was validly made to correct legitimate errors in the claims. Congress enabled a patent applicant to correct errors in a patent due to the applicant's mistake in 35 U.S.C. § 255. This section provides:

> Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

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[7]Smith & Nephew contends that its accused products, however, do not infringe the original claims of the '882 patent. (See also D.I. at 1110)

35 U.S.C. § 255 (2000). This section enumerates two specific kinds of applicant error which may be corrected through a certificate of correction: (1) errors of a clerical or typographical nature; and (2) errors of a minor character. The Federal Circuit has noted that the words of § 255 do not preclude broadening corrections. Superior Fireplace Co. v. The Majestic Prods. Co., 270 F.3d 1358, 1371 (Fed. Cir. 2001). However, the Federal Circuit opined that " a broadening correction of a clerical or typographical error [may] be allowed only where it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected." Id. at 1373. With regard to mistakes of a minor character, the Federal Circuit has interpreted the language of § 255 to exclude mistakes that broaden a claim. Id. at 1374. The Federal Circuit further has held that the clear and convincing standard is applicable to challenges to the validity of a certificate of correction. Id. at 1367.

Applying these principles to the facts at bar, the court notes that Mr. John Raffle, Arthrocare's in-house counsel, filed an amendment on March 25, 1997 prior to the '882 patent grant to change the phrase "active electrode" to "electrode terminal." Mr. Raffle testified that he attempted to make this change for every occurrence of the phrase "active electrode" in the claims. (See D.I. 417 at 1524-26) Mr. Raffle also testified that the

phrase "the active electrode" in uncorrected application claim 23 lacked antecedent basis because the precise words "an active electrode" did not appear earlier in the claim set. (See id. at 1515-16) Based upon this testimony, the jury could have inferred that Mr. Raffle inadvertently overlooked two occurrences of the phrase "active electrode" in his amendment and that reference to "the active electrode" after the phrase "an electrode terminal" was a typographical error. A jury likewise reasonably could have concluded that both the typographical error and the proper way to correct it were evident in light of the prosecution history of the '882 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the certificate of correction is invalid.

With respect to a new trial, the weight of the evidence does not warrant a new trial to avoid a miscarriage of justice. Arthrocare offered sufficient evidence upon which a jury could have found that the certificate of correction is valid. Hence, the court denies Smith & Nephew's motion for a new trial premised on the invalidity of the certificate of correction for the '882 patent.

### C. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Contributory and Inducing Infringement Grounds

#### 1. The Legal Standard for Contributory Infringement

The doctrine of contributory infringement is codified at 35 U.S.C. § 271(c):

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

The Federal Circuit has explained that this form of infringement is premised on the idea that a defendant who displays sufficient culpability should be held liable as an infringer, even though he did not technically make, use, or sell a patented invention. Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990). The Federal Circuit also has noted that "[s]uch liability was under a theory of joint tortfeasance, wherein one who intentionally caused, or aided and abetted, the commission of a tort by another was jointly and severally liable with the primary tortfeasor." Id. Based upon the language of § 271(c), there can be no contributory infringement in the absence of direct infringement. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341-42 (1961). In addition,

there can be no contributory infringement without knowledge that the component made or sold was especially adapted for a particular use proscribed by a known patent. See Hewlett-Packard Co., 909 F.2d at 1469. Actual intent to cause or contribute to infringement is not necessary to establish contributory infringement. Id. Instead, "[a] seller of a 'material part' of a patented item may be a contributory infringer if he makes a non-staple article that he knows was 'especially made or especially adapted for use in an infringement of such patent.'" Husky Injection Molding Sys. v. R&D Tool & Eng'g Co., 291 F.3d 780, 784 (Fed. Cir. 2002) (citing 35 U.S.C. § 271(c); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 219 (1980)). Furthermore, the "occasional and aberrant use of these products, [even] where they are clearly designed to be used in a system specified in the claims of a patent, does not rise to the level of 'a staple article or commodity of commerce suitable for substantial non-infringing use.'" Preemption Devices v. Minnesota Mining & Mfg. Co., 630 F. Supp. 463, 471 (E.D. Pa. 1985) (citing Dennison Mfg. Co. v. Ben Clements & Sons, Inc., 467 F. Supp. 391, 428 (S.D.N.Y. 1979)).

**2. The Legal Standard for Inducing Infringement**

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." As with contributory infringement, direct infringement is a

prerequisite to inducing infringement. Met-Coil Sys. Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 687 (Fed. Cir. 1986). Additionally, the alleged infringer must have knowingly induced infringement. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990)(citing Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)). The Federal Circuit has stated that "although section 271(b) does not use the word 'knowing, the case law and legislative history uniformly assert such a requirement." Water Techs, 850 F.2d at 668. In this regard, mere knowledge of the acts alleged to constitute inducement is not enough. Manville Sales Corp., 917 F.2d at 553. Rather, the plaintiff has the burden of showing that "the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." Id.

### 3. The Direct Infringement Prerequisite for Contributory and Inducing Infringement[8]

Considering the direct infringement prerequisite for the acts of contributory and inducing infringement, Smith & Nephew

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[8]Smith & Nephew argues that it is not liable for contributory or inducing infringement because its accused products do not directly infringe the '536 patent. The court shall not consider this argument in the instant analysis because a jury found that Smith & Nephew directly infringed the '536 patent and the court herein denied Smith & Nephew's motion for judgment as a matter of law on direct infringement grounds for this patent. See *supra*, Section IV, 1, A.

Recall also Smith & Nephew did not argue noninfringement of the '882 patent as corrected by the certificate of correction.

argues that the Saphyre, Control RF, and ElectroBlade probes do not practice the limitations of asserted claims of the '592 patent. Specifically, Smith & Nephew contends that the return electrodes on its products frequently contact target tissue during the performance of the method for applying electrical energy recited in claims 1 and 23 of the '592 patent.[9] Claim 1 requires "positioning a return electrode . . . such that [it] is not in contact with the body structure," and claim 23 requires "spacing a return electrode away from the body structure." ('592 patent, col. 24 at ll. 13-14; col. 25 at ll. 48) Smith & Nephew alleges that Dr. Goldberg improperly applied a temporal limitation in testifying that the "only way not to infringe this claim with the device is to make sure that the return electrode . . . is always in contact **when the energy is on.**" (D.I. 411 at 421-22)(emphasis added) Smith & Nephew particularly notes that the return electrodes on its products contact tissue while the probe is being positioned before energy is applied (i.e., during the second step enumerated in claims 1 and 23). Smith & Nephew, therefore, advocates that a reasonable jury could not find that

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[9]Procedurally, Smith & Nephew raised the issue of direct infringement of the '592 patent in a motion for judgment as a matter of law. As the court previously noted above, this issue was not presented to the jury. See *supra*, Introduction, n. 1. The court, therefore, construes Smith & Nephew's argument in the context of its motion for judgment as a matter of law on both contributory and inducing infringement grounds.

the use of any of its accused products satisfies the return electrode "not in contact/spaced away" limitations given this contact time. (See D.I. 354 at 7)

Viewing the record in a light most favorable to Arthocare as the non-moving party, the court disagrees with Smith & Nephew's argument. The record reflects that there are times when the return electrode is not in contact with target tissue and all of the other claim limitations are performed, thereby supporting the jury verdict of literal infringement. To this end, Smith & Nephew's expert, Dr. Michael Choti, admitted that when the active electrode on the Control RF probe is positioned near the target site and energy is applied, the return electrode does not always contact tissue. (See D.I. 412 at 743-744) Ms. Karen Drucker, the ElectroBlade project manager, and Ms. Kate Knudsens, the Saphyre project manager, similarly acknowledged that video clips of the accused products in operation show times when the return electrodes of the ElectroBlade and Saphyre probes, respectively, were not in contact with tissue while energy was applied. (See D.I. 415 at 1036, 985) Mr. Warren Heim, Smith & Nephew's consultant, also testified that the Control RF probe was designed so that the return electrode would not contact tissue during use. (See D.I. 414 at 957-58) Additionally, Mr. Joe McCreary, the Saphyre marketing manager, testified that the Saphyre can function even if the return electrode is not in contact with

tissue. (See D.I. 412 at 555) Moreover, the Saphyre Sales Guide warns that "care should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft." (PX 390 at 37) The ElectroBlade Sales Training CD likewise instructs users to "ensure that the entire tip including the return electrode is immersed in saline, to "present" the active electrode to the tissue, and "to use suction to pull bleeding tissue to the blade for coagulation." (PX 199 at 11, 7) The Control RF "Instructions for Use" further informs doctors to be sure that the active and return electrodes are "completely surrounded" by electrically conducting fluid during use." (PTX 205 at 1) Considering the totality of this evidence, a jury reasonably could have found that Smith & Nephew's accused products meet the "not in contact/spaced away" limitations of the asserted claims and thereby directly infringe the '592 patent.

**4. Contributory Infringement**

Smith & Nephew asserts that its products have "substantial non-infringing uses" such that they were not designed to infringe the asserted claims of the patents in suit. Specifically, Smith & Nephew claims that these non-infringing uses include: (1) operation of the probes to apply energy while the return electrode touches tissue (i.e., noninfringement of the '592 patent); (2) operation of the probes to apply energy without creating a vapor layer, thereby achieving coagulation instead of

ablation (i.e., noninfringement of the '882 patent); and (3) operation of the probes as part of an "electrosurgical system" that does not have a fluid supply (i.e., noninfringement of the '536 patent).

The court is again unpersuaded by these arguments. The evidence of record for the '592 patent discussed above shows that the Saphyre, ElectroBlade, and Control RF probes were constructed to prevent the return electrode from contacting tissue. The court finds that similar evidence exists with respect to the '882 and '536 patents. In particular, Smith & Nephew refers to its Saphyre product line as "ablation" probes in its sales guides. (See PX 381 at 1, PX 390 at 10). Smith & Nephew also markets its Saphyre and Control RF probes for use in ablation, not coagulation, even though both may provide coagulation. (See PX 390 at 4, PX 593 at 11, 29, PX 205 at 1) Additionally, several witnesses at trial testified that the Saphyre, ElectroBlade, and Control RF probes must be used with electrically conducting fluid. (See D.I. 411 at 397-98, 405, 412; D.I. 414 at 848; D.I. 415 at 1013) More specifically, Mr. Sparks and Ms. Drucker testified that electrically conducting fluid must be delivered to the target site in arthroscopic surgery. (See D.I. at 814-16; D.I. 415 at 1013-14) A reasonable juror, taking all of this evidence into account, could have concluded that the accused probes were designed to infringe and that the occasional or

aberrant use of one of them in a non-infringing manner, as suggested by Smith & Nephew, does not constitute a substantial noninfringing use. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for contributing to the infringement of the patents in suit.

As to a new trial, none of the reasons for granting a new trial exists in the instant case. That is, the jury's verdict is not against the weight of the evidence. Rather, both sides presented evidence to support their respective positions. Additionally, no miscarriage of justice will result by upholding the jury's verdict. For these reasons, the court denies Smith & Nephew's motion for a new trial on contributory infringement grounds.

**5. Inducing Infringement**

Smith & Nephew argues that it is not liable as an inducing infringer because Arthrocare failed to prove that Smith & Nephew intends to cause its customers to infringe the asserted claims of the patents in suit. The court finds that Smith & Nephew's arguments are not well founded and that sufficient evidence exists in the record to support the jury's verdict of inducing infringement. In particular, Ms. Knudsen and Mr. Heim testified that they read the patents in suit before the Saphyre probe design was complete and prior to design efforts commenced for the ElectroBlade and Control RF probes. (D.I. 415 at 991; D.I. 414

at 936-37, PX 735 at 23-25) They further stated that they evaluated Arthrocare's patented products prior to designing the accused products. (D.I. 414 at 951, D.I. 415 at 977-78) On this basis, a jury reasonably could have found that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit when using the Saphyre, ElectroBlade, and Control RF probes. Consequently, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for inducing infringement.

Regarding a new trial, the jury's verdict of inducing infringement is not against the clear weight of the evidence. Moreover, no miscarriage of justice will result if this verdict stands. Accordingly, the court concludes that a new trial is not warranted and denies Smith & Nephew's motion for a new trial on inducing infringement grounds.

### D. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Invalidity Grounds

Smith & Nephew renewed its motion for judgment as a matter of law that the patents in suit are invalid based on prior art grounds. Before reaching the substance of this motion, Arthocare challenges Smith & Nephew's right to raise this motion claiming that Smith & Nephew failed to preserve the issue of invalidity before the case was submitted to the jury pursuant to Fed. R. Civ. P. 50(a). Rule 50(b) permits consideration of such renewed

motions for judgment as a matter of law only when a motion for a directed verdict has been made at the close of the evidence offered by an opponent. In pertinent part, Rule 50(b) states:

> If, for any reason, the court does not grant a motion for judgment as a matter of law made at the close of all the evidence, the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion. The movant may renew its request for judgment as a matter of law by filing a motion no later than 10 days after entry of judgment.

Rule 50(a) requires that "[a] motion for a directed verdict shall state the specific grounds therefor." This requirement is in place to afford the non-moving party with the opportunity to reopen its case and present additional evidence. See Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 814 (3d Cir. 1984)(citing Lowenstein v. Pepsi-Cola Bottling Co., 536 F.2d 9, 11 (3d Cir. 1976)).

In the case at bar, Smith & Nephew motioned for a directed verdict three times. It first made a Rule 50(a) motion at the close of Arthrocare's case. (See D.I. 415 at 1161) It made a second Rule 50(a) motion at the close of all the evidence. (See D.I. 417 at 1549) Smith & Nephew then renewed this motion prior to the jury charge. (See D.I. 418 at 1700) Since the issue of invalidity had not been presented when Smith & Nephew initially moved for a directed verdict, the court finds that Smith & Nephew's first motion was not directed to the invalidity of the patents in suit. The court notes, however, that the issue of

invalidity was in evidence at the time Smith & Nephew made its second and third motions. The court also notes that it indicated after these latter motions that Smith & Nephew's rights were reserved, despite the fact that Smith & Nephew did not specifically state the precise grounds for its motions. (See D.I. 417 at 1549; D.I. 418 at 1700). As well, the court did not require any argument concerning the motions when raised and precluded Smith & Nephew from discussing them. The court, therefore, concludes that it would be unjust to Smith & Nephew not to consider its renewed motion for judgment as a matter of law. Accordingly, the court will consider the instant motion.

**1. The Legal Standard for Invalidity**

A patent is presumed valid, and each claim whether in independent, dependent, or multiple dependent form is presumed to be valid independent of the validity of other claims. 35 U.S.C. § 282 (2003). The party asserting invalidity, consequently, has the burden of proof. Id. This burden is satisfied only by proving facts establishing invalidity by clear and convincing evidence. Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003) (citing Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1569 (Fed. Cir. 1996)). The patentee, therefore, need not submit any evidence to support the validity of a patent. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1570 (Fed.

Cir. 1986). Moreover, the challenger's burden is especially difficult to meet when the art relied on at trial was considered by the PTO. BOC Healthcare, Inc. v. Nellcor, Inc., 892 F. Supp. 598, 602 (D. Del. 1995). Indeed, the Federal Circuit has stated:

> When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984).

**a. Invalidity on Anticipation Grounds**

A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference explicitly discloses each and every limitation of the claimed invention. Lamar Marine, Inc. v. Baronet, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). The Federal Circuit has stated that "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991). In determining whether a patented invention is explicitly anticipated, the claims are read in the context of the patent specification in which they arise and in which the invention is described. Glaverbel Societe Anonyme v.

Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed. Cir. 1995). The prosecution history and the prior art may be consulted if needed to impart clarity or to avoid ambiguity in ascertaining whether the invention is novel or was previously known in the art. Id.

A prior art reference also may anticipate without explicitly disclosing a feature of the claimed invention if that missing characteristic is inherently present in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. Id. That is, "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. The Federal Circuit also has observed that "[i]nherency operates to anticipate entire inventions as well as single limitations within an invention." Schering Corp. V. Geneva Pharms. Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003). Moreover, recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. Id. at 1377.

An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. See Key Pharms. v. Hercon Labs Corp., 161 F.3d 709, 714

(Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art. Id. A finding of anticipation will invalidate the patent. Applied Med. Res. Corp. v. U.S. Surgical Corp., 147 F.3d 1374, 1378 (Fed. Cir. 1998)

**i. The '536 Patent**

Smith & Nephew charges that the '536 patent is anticipated by several prior art references. In particular, Smith & Nephew contends that the '499 patent, the '007 patent, the '198 patent, and the Elsasser/Roos article each disclose all of the limitations of the invention claimed in the '536 patent. As support for its anticipation argument, Smith & Nephew asserts that its expert Dr. Taylor testified that the '198, '499, and '007 patents and the Elsasser/Roos article individually disclose every limitation recited in claims 45, 46, and 56 of the '596 patent. (See D.I. 416 at 1294-1313) Smith & Nephew also contends that Arthocare did not offer any evidence to contradict or rebut this testimony, but instead cross-examined Dr. Taylor about select claim limitations to confuse and mislead the jury.

Viewing the record in a light most favorable to Arthocare as the verdict winner, the court is unpersuaded by Smith & Nephew's argument. The evidence presented at trial reasonably supports the jury's verdict of infringement. The PTO specifically considered the prior art effect of the '499 and '007 patents during the prosecution of the '536 patent and allowed the

asserted claims. The PTO alsc considered the '198 patent and the Elsasser/Roos article during the reexamination of the '536 patent and issued a notice of intent to issue reexamination certificate. (See D.I. 417 at 1537-1540) The court concludes that this evidence was sufficient to convince a jury of the validity of the '536 patent.

Additionally, Arthocare solicited testimony from Dr. Taylor establishing that each of the asserted references fails to disclose at least one limitation of the asserted claims. Dr. Taylor admitted on cross-examination that the '499 patent does not disclose a current flow path through electrically conducting fluid as required by the asserted '536 claims. Dr. Taylor testified that it instead discloses inserting the electrodes directly into the target tissue, thereby facilitating electrical current flow between the axial and outer electrodes through the tissue. (See D.I. 416 at 1409-12) Dr. Taylor also stated in his deposition that both electrodes disclosed in the '007 patent have substantially the same current density (i.e., meaning that the '007 patent did not disclose a return electrode), though asserted at trial that his deposition testimony was in error. (See id. at 1383-85) Dr. Taylor likewise testified that the '007 patent and the '198 patent do not disclose the location of a connector with respect to the proximal end of the shaft as required by the asserted claims. (See id. at 1400; 1371) Additionally, Dr.

Taylor testified that the Elsasser/Roos article fails to explicitly describe the function for the structure located at the proximal end of the disclosed probe. (See id. at 1298) Dr. Taylor further testified on cross-examination that neither the '198 patent nor the Elsasser/Roos article disclose the use of either saline or Ringer's lactate, both of which are electrically conducting fluids. (See id. at 1340-43) Dr. Taylor, in fact, stated that the references do not distinguish between the electrically non-conducting liquid used with monopolar devices and the liquid used in bipolar devices. (Id.) Moreover, Dr. Taylor stated that there would be no need for the steel band described in Figure 5 of the '198 patent if the liquid shown in Figure 5 was electrically conducting. (See id. at 1345) Given the totality of this evidence, a jury may have properly found that the prior art references do not anticipate the '536 invention. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that the asserted claims of the '536 patent are invalid on anticipation grounds.

With respect to a new trial, no miscarriage of justice will result if the jury's verdict of validity as to the '592 patent stands. Mindful not to substitute its own judgment of the facts and the credibility of the witnesses for those of the jury, the verdict is neither against the weight of the evidence nor facially inconsistent. Furthermore, since the conclusion of

trial, no new evidence has surfaced to alter the outcome of the trial. The court, consequently, denies Smith & Nephew's motion for a new trial on anticipation grounds for the '592 patent.

**ii. The '882 Patent**

Smith & Nephew contends that the '138 patent and the Slager article individually disclose each and every limitation recited in the asserted claims of the '882 patent. Smith & Nephew specifically argues that the '138 patent anticipates claims 1, 13, and 54 and that the Slager article anticipates claims 1, 13, 17, and 54. Smith & Nephew relies on the expert testimony of Dr. Taylor and Dr. Kim Manwaring for support. (See id. at 1313-1320; D.I. 414 at 886-96) As with the '536 patent discussed above, Smith & Nephew maintains that Arthocare failed to present rebuttal evidence to contradict the experts, but instead misleadingly cross-examined these experts regarding particular claim limitations to confuse the jury.

The court, nonetheless, finds that a reasonable jury could have concluded on the record before it that several differences exist between the '882 invention and the '138 patent and the Slager article such that Smith & Nephew failed to prove anticipation by clear and convincing evidence. Focusing first on the '138 patent, Dr. Manwaring admitted that this reference discloses a spark discharge followed by vaporization of the fluid. (See id. at 907-908) In contrast, claims 1, 13, 17, and

54 of the '882 patent disclose vaporization of the electrically conducting fluid followed by electrical discharge. Claim 13 also requires generation of photons having a wavelength in the ultraviolet spectrum. Dr. Manwaring stated at trial that the '138 patent does not explicitly mention ultraviolet photons and that he was unaware of any testing that established that the '138 device emits ultraviolet photons. (See id. at 897-98) Similarly, Dr. Taylor confirmed that he performed no testing to establish that a device built according to the '138 patent generates ultraviolet light. (See D.I. 416 at 1420-21) Finally, claim 54 of the '882 patent discloses evacuating the fluid beyond the vicinity of the target tissue. Both Dr. Manwaring and Dr. Taylor admitted that the '138 patent, in contrast, discloses drawing the fluid into the catheter tip where it remains in the vicinity of the target tissue. (See D.I. 414 at 904-05; D.I. 416 at 1432-33)

Turning to consider the Slager article, Dr. Taylor agreed that it does not disclose the application of energy to a "target site on a patient body structure" as required by the preamble of claims 1 and 28. Dr. Taylor instead testified that the Slager article discussed the application of energy to a tissue in a lab dish. (See id. at 1426-27) Since sufficient evidence exists for the jury to have concluded that the '138 patent and the Slager article do not disclose each and every limitation found in the

claims of the '882 patent, Smith & Nephew is not entitled to prevail on its motion for judgment as a matter of law. The court, consequently, denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on anticipation grounds.

Addressing Smith & Nephew's motion for a new trial on anticipation grounds, Smith & Nephew has failed to demonstrate that the verdict is against the weight of the evidence or that a new trial is necessary to remedy a miscarriage of justice. For these reasons, the court denies Smith & Nephew's motion for a new trial on anticipation grounds as to the '882 patent.

**iii. The '592 Patent**

Smith & Nephew asserts that the '007 patent and the Slager article each recite all the limitations of the asserted claims of the '592 patent. Smith & Nephew relies on Dr. Taylor's testimony to support this anticipation argument and, as with the '536 and 882 patents, again claims that Arthocare failed to elicit any rebuttal testimony. Rather, Smith & Nephew charges that Arthocare misleadingly cross-examined Dr. Taylor regarding certain claim limitations to cause confusion among the jurors.

Substantial evidence exists in the record to distinguish the '592 invention from the cited prior art references in support of the jury's verdict of validity. The '592 patent contains the same "return electrode" limitation as the '536 patent. As

discussed above in relation to the '536 patent, the '007 patent does not disclose a return electrode limitation. Additionally, the '007 patent fails to disclose the waveform necessary to determine whether it anticipates the 500 to 1,400 volts peak to peak recited in claim 21.[10] Dr. Taylor admitted that when he opined that the '007 patent discloses a voltage in the range of 500 to 1,400 volts peak-to-peak, he presumed that the wave form was a sine wave since this is the most common form used. (See id. at 1401-1404) In light of this presumption, a jury reasonably may have dismissed Dr. Taylor's testimony concerning the anticipatory effect of the '007 patent on the '592 patent. As to the Slager article, claims 1 and 28 of '592 patent contain the same "on or within a patient's body" preamble language as claims 1 and 26 of '882 patent. The Slager article, on the other hand, only discloses the application of energy to tissue in a lab dish as noted above. Furthermore, claims 1 and 23 of the '592 patent specify that the return does not touch the body structure. Dr. Taylor testified that he was unable to determine the location

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[10]The '007 patent discloses a 20 to 200 root-mean-square voltage. Presume that the wave form produced by the generator is a sine wave, the court acknowledges that this root-mean-square voltage range may be converted to a peak-to-peak voltage using a 2.83 conversion factor. Applying this factor to the voltage range disclosed in the '007 patent, the resulting peak-to-peak voltage for the 200 volts root mean square is 583 volts peak-to-peak. However, using the conversion factor of 2 for a square wave, the 200 volts root-mean-square converts to 400 volts peak-to-peak.

of the return electrode in the Slager article. (See id. at 1414-18) Given this evidence of the differences between these prior art references and the claimed invention, the jury verdict was not erroneous. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '592 patent is invalid on anticipation grounds.

The court also denies Smith & Nephew's motion for a new trial as to the '592 patent. None of the common reasons for granting a new trial exist under the facts at bar. That is, the jury's verdict is not against the weight of the evidence or facially inconsistent. Likewise, no miscarriage of justice will result if the verdict stands.

**b. Invalidity on Enablement Grounds**

The statutory basis for the enablement requirement is found in 35 U.S.C. § 112, paragraph 1, which provides in relevant part:

> The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In order to be enabling, a specification must teach those skilled in the art how to make and to use the full scope of the claimed invention without undue experimentation. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997). The Federal Circuit has explained that "patent protection is granted in

return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable ... Tossing out the mere germ of an idea does not constitute enabling disclosure." Id. at 1366.

In determining whether undue experimentation is required to practice a claimed invention, a court may consider several factors, including: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (6) the predictability of the art; and (7) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Consideration of each of these factors, however, is not a mandatory part of a court's analysis. Rather, a court is only required to consider those factors which are relevant to the facts of each case. See Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991). Thus, the enablement requirement is a question of law based on underlying factual inquiries. In re Wands, 858 F.2d at 737.

Smith & Nephew argues that the asserted claims in the '882 patent are not properly enabled because the "cold ablation"

process is not adequately described in the specification.[11] The '882 specification states that the cold ablation process is dependent upon a variety of factors including "the number of electrode terminals, electrode size and spacing, electrode surface area, asperities and sharp edges on the electrode surfaces, electrode materials, applied voltage and power, current limiting means, such as inductors, electrical conductivity of the fluid in contact with the electrodes, density of the fluid, and other factors." ('882 patent, col. 11 at ll. 8-13) Smith & Nephew contends that while the requisite variables are enumerated in the specification, it fails, nevertheless, to specify what particular combination should be used to achieve optimal cold ablation. Smith & Nephew supports this argument with Dr. Taylor's testimony regarding preferred voltage ranges, materials, frequencies, fields, power levels, contract surface area values and distances for the active electrode. (See D.I. 416 at 1436-38)

The jury, however, reasonably may have disregarded Dr. Taylor's testimony, finding it to be both conclusory and entirely solicited by counsel's line of direct questioning. Dr. Taylor testified that he "blanked" on invalidity grounds other than

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[11]The cold ablation process involves "applying a high frequency voltage between the active electrode and the return electrode to develop high electric field intensities in the vicinity of the target tissue site." ('882 patent, col. 10 at ll. 41-44) The high electric field causes the tissue to completely disintegrate. (Id. at ll. 44-54)

anticipation; consequently, he was led into a discussion of enablement by trial counsel. In relevant part, Dr. Taylor testified as follows:

> Q: Do you have any other basis for believing that the claims of the '882 patent are invalid?
> A: **I am sorry, I am blanking on this.**
> * * *
> Q: Does the '882 patent teach anything about how to achieve a new phenomenon that is different than the principle of operation of conventional electrosurgical devices?
> A: No, it doesn't. I was perplexed and, frankly, am still perplexed about the overall phenomenon of [c]oblation.
> Q: And is that defense also sometimes called nonenablement?
> A: Yes, it is.
> Q: Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?
> A: Yes, I have an opinion.
> Q: What is that opinion?
> A: That it is not.
> Q: Thank you.

(Id. at 1323-1325)(emphasis added) Based on the above record, the jury had sufficient grounds to conclude that Smith & Nephew had failed to prove by clear and convincing evidence that the '882 patent was not enabled and invalid. In turn, the court denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on enablement grounds.

Regarding a new trial, the verdict was not against the clear weight of evidence. Likewise, the jury's verdict will not lead to a miscarriage of justice. Thus, the court denies Smith &

Nephew's motion for a new trial on enablement grounds as to the '882 patent.

### E. Smith & Nephew's Motion for A New Trial on the Basis of Improperly Admitted/Excluded Evidence

Smith & Nephew contends that the court erred in admitting and excluding select evidence such that a new trial is warranted. Specifically, Smith & Nephew argues that the following evidence was improperly excluded: (1) Arthrocare's sworn 510(k) submissions to the Food and Drug Administration ("FDA"); (2) testimony regarding those submissions from Dr. Hira A. Thapliyal, a co-inventor named on the patents in suit; (3) testimony regarding the certificate of correction from Mr. Warren Heim, a consultant to Smith & Nephew from Team Medical; (4) Judge Orrick's opinion that the '198 patent anticipated one of the patents in suit; and (5) testimony from Dr. Manwaring regarding ultraviolet photon emission test results. Smith & Nephew also contends that evidence of copying and Smith & Nephew marketing documents were improperly admitted. Federal Rule of Civil Procedure 61 requires a court to disregard harmless evidentiary errors. In pertinent part, Rule 61 states:

> No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial . . . unless refusal to take such action appears to the court inconsistent with substantial justice. The court at every stage of the proceeding must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.

A court's inquiry in evaluating a motion for a new trial on the basis of trial error is, therefore, twofold: "(1) whether an error was in fact committed, and (2) whether that error was so prejudicial that denial of a new trial would be 'inconsistent with substantial justice.'" Finch v. Hercules Inc., 941 F. Supp. 1395, 1414 (D. Del. 1996) (internal citation omitted). With respect to the second prong of this two-part test, a new trial must be granted unless "it is highly probable that [the erroneous ruling] did not affect the [objecting party's] substantial rights." Bhaya v. Westinghouse Electric Corp., 709 F. Supp. 600, 601 (E.D. Pa. 1989) (quoting McQueeney v. Wilmington Trust Co., 779 F.2d 916, 928 (3d Cir. 1985)).

The court has reviewed its rulings concerning the evidence in issue consistent with the first prong and finds no error was in fact committed. As such, the court need not consider whether denial of a new trial would be inconsistent with substantial justice as set forth in the second prong. The court considers each item of evidence in dispute in further detail below.

**1. Exclusion of Arthrocare's FDA 510(k) Submissions and Dr. Thapliyal's Testimony**

Smith & Nephew argues that Arthrocare's 510(k) submissions to the FDA and Dr. Thapliyal's testimony regarding those submissions qualify as admissions against interest by a party opponent and should have been admitted into evidence as relevant

to the issues of anticipation and enablement.[12] In particular, Smith & Nephew charges that the submissions demonstrate that the commercial embodiments of the patents in suit have the same principles of operation as prior art devices. The court rejects Smith & Nephew's argument and maintains that these submissions are irrelevant to invalidity, just as the court originally concluded when it ruled on Smith & Nephew's motion in limine. (See D.I. 367 at ¶15; D.I. 410 at 193) Anticipation is determined by comparing the limitations of the asserted claims, not of commercial embodiments as described in 510(k) submissions, to the disclosure found in a single piece of prior art. Enablement is evaluated based on the teachings found in the specification, not on those present in 510(k) submissions. Therefore, since the 510(k) submissions are not relevant to the substantive issues at bar, the exclusion of these documents and corresponding testimony was not in error. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Arthrocare's 510(k) submissions and Dr. Thapliyal's testimony about these submissions.

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[12]A 510(k) submission to the FDA is a "submittal[] of engineering and clinical information which [is] provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market." Sunrise Med. HHG, Inc. v. AirStep Corp., 95 F. Supp. 2d 348, 405 (W.D. Pa. 2000).

### 2. Exclusion of Mr. Heim's Testimony

Smith & Nephew argues that it sought to introduce testimony at trial from Mr. Heim to support its argument that the certificate of correction was invalid. Specifically, Smith & Nephew contends that Mr. Heim was prepared to testify that he did not recognize the possibility of an error in the "active electrode" claim language found in the '882 patent as originally issued prior to the certificate of correction. On review, the court finds that its decision to limit Mr. Heim's testimony to the subject matter of his deposition was correct.

Federal Rule of Civil Procedure 37(c)(1) provides in pertinent part:

> A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.

The court excluded this testimony because Mr. Heim did not discuss the substance of his trial testimony in his deposition. That is, approximately one week prior to the start of trial, Arthocare deposed Mr. Heim and asked him what he expected to testify about at trial. Smith & Nephew counsel instructed Mr. Heim not to respond to the question citing attorney-client privilege and the work product doctrine. Finding such instruction to be improper gamesmanship under Rule 37(c), the

court limited Mr. Heim's testimony to the substance of his deposition testimony. (See D.I. 413 at 944) Additionally, the court is troubled by Smith & Nephew's use of Mr. Heim's testimony. Despite identifying him as a fact witness, Smith & Nephew appears to employ him as an expert concerning the validity of the certificate of correction. (See id. at 939) In light of both these concerns, the court denies Smith & Nephew's motion for a new trial on grounds that Mr. Heim's testimony was improperly limited.

### 3. Exclusion of Judge Orrick's Opinion

Smith & Nephew argues that the findings of fact relating to the '536 and '882 patents made by Judge Orrick following a preliminary injunction hearing during the course of the Arthocare v. Ethicon, Inc. litigation are relevant to both the presumption of validity and the validity of the '536 and '882 patents. In particular, Smith & Nephew charges that Judge Orrick's determination that the '198 patent describes "a bipolar electrosurgery device intended to be used in electrically conductive fluid, with electrical current flowing between the active and return electrodes through the fluid" should have been admitted since the parties at bar dispute whether the '198 patent discloses electrically conducting fluid. (D.I. 321, ex. A at 17) The court disagrees. Judge Orrick rendered his findings of fact in the context of a preliminary injunction motion and concluded

that there were substantial questions about the validity of claim 45 of the '536 patent, claims 1, 26, 28, and 32 of the '882 patent, claims 40 and 44 of the '909, and claim 101 of the '281 patent. His interlocutory decision does not alter the presumption of validity; a patent is presumed valid and remains so unless and until final judgment is entered otherwise. See 35 U.S.C. §282 (2003). Additionally, findings of fact made in litigation unrelated to the present suit do not have a presumptive effect. In the instant litigation, the jury was charged with determining the validity of the asserted patents after considering the evidence presented at trial in accordance the court's instructions. Any reference to Judge Orrick's opinion potentially would have confused the jury regarding their role in deciding such validity. Moreover, the burdens of proof associated with a preliminary injunction hearing differ from those employed at trial. In this regard, the Federal Circuit has observed that "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." Amazon.com v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1358 (Fed. Cir. 2001). Consequently, the court denies Smith & Nephew's motion for a new trial on the basis the exclusion of Judge Orrick's opinion.

### 4. Limitation of Dr. Manwaring's Testimony To His Expert Report

Smith & Nephew contends that Dr. Manwaring should have been permitted to testify at the trial about whether the Codman ME2[13] emits ultraviolet photons and about testing conducted by Dr. Skromee to prove such emission. Smith & Nephew argues that this testimony was relevant to enable the jury to assess whether the Codman ME2 anticipates the asserted claims that have ultraviolet photon emissions as a limitation. However, Smith & Nephew did not produce Dr. Skromme's report until two days before Dr. Manwaring was scheduled to testify after the start of trial. Because Arthrocare was not afforded the opportunity to take discovery on the test results or to depose Dr. Skomme, the court excluded such evidence at trial, consistent with Rule 37(c)(1). The court, therefore, denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Dr. Manwaring's testimony about ultraviolet photon emission testing.

### 5. Admission of Evidence of "Copying"

Smith & Nephew argues that admission of evidence of "copying" infected the entire trial and improperly inflamed the jury. In this regard, Smith & Nephew employees read the patents in suit and evaluated Arthrocare's patented products prior to

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[13]The Codman ME2 is a commercial product embodied by the '158 or '138 prior art patent.

designing the accused products. (See D.I. 412 at 626-633; D.I. 415 at 1160-61; D.I. 417 at 1507-1508)

Prior to trial, in order to avoid any inferences of copying, Smith & Nephew made the strategic decision to withdraw its defense of obviousness and to stipulate to its knowledge of the patents in suit. Nevertheless, after a vigorous motion practice and lengthy discussions, the court concluded that the evidence was still relevant to the issue of inducing infringement. More specifically, in order to prove that Smith & Nephew induced infringement, it was Arthrocare's burden to prove that Smith & Nephew intended to encourage or to instruct its customers to directly infringe. Evidence of copying was appropriate circumstantial evidence going to intent; that is, if Smith & Nephew used Arthrocare's patented products as a template for its own, that would be circumstantial evidence that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit by using the Saphyre, ElectroBlade, and Control RF probes.[14]

At trial, Smith & Nephew presented evidence that it is customary and not inappropriate to evaluate competitors'

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[14]It is ironic that Smith & Nephew, post-trial, argues that Arthrocare has not satisfied its burden of proving intent, based on the very evidence described above. See *supra*, Section IV, C, 5. Clearly, then, the fact of knowledge is not a sufficient basis for proving inducement and the evidence of intent is relevant.

products, and that it designed its own products without copying Arthrocare's patented products. (See D.I. 412 at 651-54; D.I. 414 at 951-53; D.I. 417 at 1507-08) Smith & Nephew was not prejudiced with respect to its ability to present the technical merits of its noninfringement and invalidity defenses to the jury. (See, e.g., D.I. 412 at 715-32; D.I. 414 at 805-822, 883-896, 962-970; D.I. 415 at 976-983; 999-1039; 1198-1227; D.I. 416 at 1288-1334; D.I. 417 at 883-896) Arthrocare, in turn, presented evidence to the contrary. (See, e.g., D.I. 411 at 376-500) Given the time spent on this noninfringement and invalidity evidence during the course of a nine-day jury trial, it cannot be said that disputed evidence relating to "copying" was disproportionately emphasized or time-consuming.

For all of these reasons, the court concludes that it was not error to admit evidence of "copying" and that such admission does not present grounds for a new trial.

**6. Admission of Smith & Nephew Marketing Documents**[15]

[15]Smith & Nephew failed to identify precisely which marketing documents that it believes were erroneously admitted. The court, consequently, is left to presume that Smith & Nephew is uniformly referring to any marketing type of document entered into evidence including the "Dyonics Control RF System" Sales Guide, "Saphyre Bipolar Ablation Probes" Sales Guide, "Instructions for Use Dyonics Series 7000 RF Arthroscopic Probe," "Competitive Selling Arthocare," and the "Dyonics Series 9000 ElectrodBlade Resector." (See, e.g., PX 593, PX 390, PX 205, PX 324, PX 335)

Smith & Nephew claims that admission of its marketing documents, which appear to characterize Arthrocare's patent position as "strong," were irrelevant and inflammatory. Smith & Nephew contends that these documents could only be relevant to the issues of obviousness and its knowledge of the patents, but that neither were in dispute at trial.[16] Moreover, Smith & Nephew argues that the opinions of its marketing and sales personnel regarding the strength of Arthrocare's patents are irrelevant.

The court finds that Smith & Nephew's marketing documents are relevant to the inducing infringement cause of action and, as such, that it did not err in admitting this evidence at trial. As the court discussed above in relation to evidence of "copying," Smith & Nephew's marketing documents are circumstantial evidence of Smith & Nephew's intent to induce infringement. These documents show how the alleged infringing products function and give instruction how to operate them. The court concludes that such information bears upon the manner in which Smith & Nephew encouraged its users to infringe Arthrocare's patents. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis the court's admission of Smith & Nephew's marketing documents.

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[16]As mentioned above, Smith & Nephew withdrew its obviousness defense prior to trial and stipulated to its knowledge of the patents in suit during trial.

### F. Smith & Nephew's Motion for A New Trial on the Basis of The Court's Jury Instructions

Smith & Nephew asserts that the court's instruction on infringement was "hopelessly confusing" for the jury when read in light of the court's claim construction for the "contact" limitation recited in claim 47 of the '536 patent and all of the asserted claims of the '592 patent.[17] The court instructed the jury as follows concerning infringement:

> In this case, Arthocare contends that Smith & Nephew's accused products and methods literally infringe the asserted claims. In order to prove that any one of the asserted claims is literally infringed, Arthocare must prove by a preponderance of the evidence that Smith & Nephew's accused products or methods include each and every limitation of that particular claim. In other words, you must compare the features of the accused products or methods with the limitations of each asserted claim in order to determine whether the accused products or methods include each and every limitation of an asserted claim.
>
> With respect to the asserted claims of the '592 and '882 patents, the accused methods need not always practice the invention of any asserted method claim, so long as Arthocare has proven by a preponderance of the evidence that the accused methods operate in a way that meet each and every step of the method described in the claim some of the time.

(D.I. 418 at 1716) The court further instructed the jury as follows concerning the "contact" limitation:

> The claim limitation the return electrode is not in contact with the body structure is clear -- the return electrode is not to contact the body at all during the performance of the claimed method. The claimed method

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[17]Smith & Nephew objected to the these instruction at the charge conference. (See D.I. 416 at 1239-1241; D.I. 417 at 1469-1473)

> does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed.

(Id. at 1718) Specifically, Smith & Nephew appears to argue that the source of the confusion lies in the juxtaposition of the language "at all" in the infringement instruction with the language "some of the time" in the claim construction instruction. Smith & Nephew argues that the jury may have read these instructions and thought that infringement occurred if the return electrode was not always in contact with the tissue.

Where the basis for seeking a new trial is an alleged error in the jury instructions, the error must be "so substantial that, viewed in light of the evidence in the case and the charge as a whole, the instruction was capable of confusing and thereby misleading the jury." Link v. Mercedes-Benz of North America, Inc., 788 F.2d 918, 922 (3d Cir. 1986). After reviewing the jury charge as a whole in light of the evidence presented in this case, the court cannot conclude that the jury instructions confused or misled the jury into believing that the accused products infringe the asserted claims if they are not in continual contact with tissue to warrant a new trial. The court instructed the jury separately regarding infringement and its claim construction, and both instructions properly stated the law. As well, the jury was asked to complete a special verdict form that explicitly separated the types of infringement, the

patents in suit, the asserted claims of each patent, and the accused infringing products. As a result of this separation, the jury was required to make finite determinations concerning whether a particular claim in a particular patent was infringed in a particular way by a particular product. Furthermore, the court finds no evidence to suggest that the jury was "hopelessly confused." The jury did not ask the court to clarify any of its instructions or pose any questions to the court during deliberations. The jury also did not incur any difficulty in completing the special verdict form as they entered responses in all required fields. (See D.I. 405) Therefore, the court denies Smith & Nephew's motion for a new trial on the basis of the court's jury instructions.

### G. Smith & Nephew's Motion for A New Trial On the Grounds That the Validity of the Certificate of Correction Was Decided by the Jury

Smith & Nephew avers that the district court is better suited to decide the validity of the certificate of correction than a jury because such determination involves both a review of the factual determinations of a government agency and the legal decisions about the nature of the underlying mistake. The court disagrees. Smith & Nephew did not object to submitting this issue to the jury at any time during the trial or prior to the jury charge. Smith & Nephew appears now to raise this objection in the face of an unfavorable jury verdict. Even assuming,

arguendo, that the court did err in submitting this issue to the jury, the court, nevertheless, agrees with the jury's verdict that the certificate of correction is valid. The court, consequently, denies Smith & Nephew's motion for a new trial on the grounds that the validity of the certificate of correction was decided by the jury.

### H. Smith & Nephew's Motion for A New Trial on the Basis of Arthrocare's Refusal to Limit the Issues at Bar

Smith & Nephew complains that it was allocated insufficient time to adequately try the number of issues presented by Arthrocare. As described by Smith & Nephew, Arthrocare asserted sixteen claims from three patents against three Smith & Nephew products.[18] As a result, according to Smith & Nephew, the verdict form required the jury to make 107 separate factual findings, which it did in only 4.5 hours, thereby spending just over two minutes per finding.[19]

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[18]In reality, Arthrocare asserted only six independent claims from three patents. All three patents involved the same technology and contained many identical claim limitations. Indeed, two of the patents share the same specification.

[19]Making such arguments is a dangerous business in Delaware, where so many patent cases are tried. The court could, for instance, cite to the case of KLA-Tencor Corporation v. ADE Corporation, Civ. No. 00-892-KAJ, where the jury returned a verdict in February 2004 on 17 issues in approximately 37 minutes, likewise spending just over two minutes per finding. The court suspects, however, that counsel for Smith & Nephew will not be complaining about that result, since it was favorable to its client in that case.

The court starts with the proposition, not really in issue here, that a district court has the inherent power to manage its docket. See, e.g., Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 609 (3d Cir. 1995). There are a finite number of trial hours in a calendar year. If the court failed to manage its caseload, parties would get to trial in four or five years, rather than 18 to 24 months. Therefore, in every civil case, the court determines the number of hours in which each party will be required to present its evidence and arguments to the jury. This decision is based on the court's calendar, its experience, and its review of the pretrial order submitted by the parties at bar. The number of hours allocated to the instant case was fair, based upon that review.[20] The record demonstrates that it was not lack of time that dictated the results in this case,[21] but the evidence presented by Arthrocare. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of Arthrocare's refusal to limit the issues at bar.

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[20]The court had assigned several more hours to this case, but postponed trial for a day (and, thus, reduced the total number of hours available for trial) at Smith & Nephew's request. In connection with this latter request, made the day before trial commenced, the court tried to, but could not, accommodate a further postponement of trial, based on a multitude of considerations, as discussed with counsel. (See D.I. 382, 390, 409)

[21]The court notes in this regard that Smith & Nephew's decision to dismiss its obviousness defense was as much related to evidentiary concerns as it was to trial management concerns. (See D.I. 409 at 16-17; see also *supra*, Section IV, E, 5)

## I. Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct and Smith & Nephew's Cross Motion to Strike Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct[22]

Smith & Nephew alleges that Arthocare committed inequitable conduct for each of the patents in suit: (1) during the prosecution of the '592 patent by informing the examiner that the '198 patent did not disclose the use of electrically conductive fluid and by not disclosing Judge Orrick's opinion; (2)during the reexamination of the '536 patent by failing to disclose Smith & Nephew's summary judgment briefs, Dr. Taylor's expert report, and the Roos declaration directed toward the issue of invalidity, and by engaging in improper "off-the-record" telephone conversations with the examiner regarding the merits of the '536 reexamination prior to the first substantive exam; and (3) during the process of obtaining the certificate of correction for the '882 patent by making two affirmative misrepresentations and by failing to explain how the so-called "correction" would broaden the scope of the claims.[23] Smith & Nephew charges that Mr. John Raffle,

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[22]Since the parties' cross motions are interrelated and focus of the issue of inequitable conduct, the court will consider their respective arguments together.

[23]In granting the parties' request to file motions regarding inequitable conduct, the court indicated that such briefing was to be based upon the record established at trial. Therefore, to the extent that either party raised evidence not of record in their respective motions at bar, the court will ignore such evidence in deciding the instant motions. The court notes that Smith & Nephew seeks leave to depose the examiner responsible for

Arthrocare's in-house counsel responsible for prosecution of the '592 patent, misled the examiner concerning the use of electrically conductive fluid. Smith & Nephew claims that Mr. Raffle knew that claim 1 of the '198 patent recited "liquid to provide electrical conductance," but failed to call the examiner's attention to this limitation. In response to a February 29, 2000 office action issued by the examiner,[24] Mr. Raffle instead responded that "[t]he '198 patent never describes the use of 'electrically conductive fluid' during electrosurgery. The Roos '198 [p]atent only discloses the use of an unspecified 'washing liquid' that flows through the endoscope that houses the treatment and neutral electrodes. . . . The Roos '198 [p]atent does not state that the 'washing liquid' that is supplied to the region of the surgical site is electrically conductive fluid." (D.I. 428, ex. B at B23) Mr. Raffle also directed the examiner's attention to the '667 patent to substantiate his argument since this reference explains that "the device described in the

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the reexamination of the '536 patent to determine the contents of his "off-the-record" conversation with Arthrocare's in-house counsel. The court denies this request.

[24]The examiner stated:

> Claims 80, 81, 83-85 . . . are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roos . . . . The device includes a spaced return electrode as shown by Figure 1. A washing fluid passes through the axial lumen of the device. Since the return electrode is removed from the body structure, a conductive fluid must complete the current flow path.

(D.I. 428, ex. B at B17)

. . . .'198 [p]atent[] did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive." (Id. at B24) Smith & Nephew further argues that Arthrocare's inequitable conduct in connection with any one of the '592, '536, or '882 patents taints the enforceability of the remaining patents in suit. Arthocare rebuts these assertions in their entirety and moves the court to enter a judgment of no inequitable conduct.

Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the PTO. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a) (2003). This duty is predicated on the fact that "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The duty of candor, good faith, and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). A breach of this duty constitutes inequitable conduct. Mollins, 48 F.3d at 1178. If it is established that a patent applicant engaged in inequitable conduct with respect to one claim, then

the entire patent application is rendered unenforceable. Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). A trial court may look beyond the final claims to their antecedents in determining inequitable conduct. Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803 (Fed. Cir. 1990). "Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it." Kingsdown, 863 F.2d at 874 (footnote omitted).

In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; or (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the PTO. Mollins, 48 F.3d at 1178. A determination of inequitable conduct, therefore, entails a two step analysis. First, the court must determine whether the withheld information meets a threshold level of materiality. A reference is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. Allied Colloids, Inc. V. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995) (citations omitted). A

reference, however, does not have to render the claimed invention unpatentable or invalid to be material. See Merck v. Danbury Pharmacal, 873 F.2d 1418 (Fed. Cir. 1989).

After determining that the applicant withheld material information, the court must then decide whether the applicant acted with requisite level of intent to mislead the PTO. See Baxter Int'l, Inc. V. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent." Herbert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. A "smoking gun" is not required in order to establish an intent to deceive. See Merck, 873 F.2d at 1422. An inference of intent is warranted where a patent applicant knew or should have known that the withheld information would be material to the PTO's consideration of the patent application. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

Once materiality and intent to deceive have been established, the trial court must weigh them to determine whether the balance tips in favor of a conclusion of inequitable conduct.

N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1988). The showing of intent can be proportionally less when balanced against high materiality. Id. In contrast, the showing of intent must be proportionally greater when balanced against low materiality. Id.

If an original patent is found unenforceable for inequitable conduct, descendent patents which are genealogically related to the original patent, such as continuations, continuations-in-part, or divisionals, may also be rendered unenforceable. See East Chicago Mach. Tool Corp. v. Stone Container Corp., 181 U.S.P.Q. 744, 748 (N.D. Ill. 1974). This theory of unenforceability has been termed "infectious unenforceability" by district courts and recognized by the Federal Circuit. See Baxter, 149 F.3d at 1327. It is premised on the guiding principle that "the duty of candor extends through the patent's entire prosecution history," and that a breach of the duty of candor "may render unenforceable all claims which eventually issue from the same or a related application." Fox, 922 F.2d at 803-04. Charges of infectious inequitable conduct are disfavored even more than charges of inequitable conduct. Eaton Corp. v. Parker-Hannifin Corp., 2003 U.S. Dist. LEXIS 1014, *2 (D. Del. Jan. 24, 2003). To prove infectious unenforceability, an accused infringer must establish "inequitable conduct sufficient to hold at least one patent

unenforceable before [a court will] consider[] whether to hold **an** entire group of related patents unenforceable." Speedplay, Inc. V. Bebop Inc., 211 F.3d 1245, 1259 (Fed. Cir. 2000). If this threshold requirement is met, then the accused infringer must demonstrate an "immediate and necessary relation" between the alleged inequitable conduct and enforcement of the related patents. Ronald A. Katz Tech. Licensing, L.P. v. Verizon Communications Inc., 2002 U.S. Dist. LEXIS 12982, *7-8 (E.D. Pa. July 16, 2002) (internal citations omitted).

The court concludes that Arthocare did not commit inequitable conduct during the prosecution of the '592 patent, during the reexamination of the '536 patent, or in conjunction with the certificate of correction for the '882 patent. Considering the '592 patent, the court notes that the use of electrically conductive fluid is material to the patentability of the '592 invention given that it appears as a limitation in the asserted '592 patent claims. The court does not find that Mr. Raffle, however, intended to deceive the PTO concerning the '198 patent. Smith & Nephew presented no evidence of record to show that Mr. Raffle purposefully misrepresented material facts or submitted false material information about this prior art reference. Rather, the record shows that Mr. Raffle provided this prior art reference to the PTO for consideration during the prosecution of the '592 patent. (See D.I. 428, ex. B at B27)

The examiner was free to reach his own conclusions regarding the teachings contained in this reference.[25] (See id. at B23-26) Indeed, the Federal Circuit has opined that an examiner is free to accept or reject an inventor's interpretation of the teachings of a reference. Life Techs., Inc. V. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000). Mr. Raffle's statements about electrically conductive fluid merely reflected his understanding of the '198 patent.

As to Judge Orrick's opinion, the court concludes yet again that it was not material to the patentability of the '592 patent. The opinion was preliminary in nature since it was issued pursuant to Arthrocare's motion for a preliminary injunction. It likewise did not directly address the anticipatory effects of the '198 patent on the application that was granted as the '592 patent. Rather, Judge Orrick found that the '198 patent raised substantial questions as to the validity of select claims of patents other than the '592 patent, namely, the '536 patent and the '281 patent.

Even assuming, arguendo, that Judge Orrick's opinion was material, Arthocare complied with its duty of disclosure under the Manual of Patent Examining Procedure ("MPEP") Section 2001.06(c). This section states that

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[25]The examiner ultimately concluded that the '198 patent did not disclose electrically conducting fluid. (See id. at B40-41)

> [w]here the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office.. . . At a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or 'fraud,' or 'inequitable conduct' relating to the original patent, and the nature of litigation material relating to these issues. Enough information should be submitted to clearly inform the Office of the nature of the issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation.

MPEP § 2001.06(c) (2003). Arthocare submitted a list of documents from the Arthocare v. Ethicon, Inc. litigation to the PTO. This list included Judge Orrick's opinion. (See id. at B7, ¶40) The court cannot conclude that Arthocare intended to deceive the PTO concerning Judge Orrick's opinion given its compliance with Section 2001.06(c). Accordingly, the court grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '592 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '592 patent.

Turning to the '536 patent, the court finds that Arthocare did not intend to deceive the PTO concerning its suit against Smith & Nephew or conceal Smith & Nephew's primary arguments concerning validity and enforceability. In compliance with Section 2001.06(c), Arthocare notified the PTO about the litigation at bar and presented Smith & Nephew's invalidity

arguments in three separate communications, namely: (1) an Information Disclosure Statement dated October 12, 2001 disclosing Smith & Nephew's primary invalidity and unenforceability arguments; (2) a second Information Disclosure Statement dated June 6, 2002 disclosing Smith & Nephew's June 3, 2002 supplemental invalidity contentions in the form of Smith & Nephew's response to Arthrocare's contention interrogatories; and (3) a third Information Disclosure Statement dated December 19, 2002 attaching Smith & Nephew September 10, 2002 invalidity contentions. (See D.I. 428, ex. B at 76-87; 97-230; 290-341) Although these disclosures did not specifically include the summary judgment motions or expert reports in dispute, such documents were cumulative in nature with Smith & Nephew's invalidity contentions already before the PTO. Rule 56(b) states that "information is material to patentability in a reexamination proceeding when it is not cumulative to information already of record or being made of record in the reexamination proceeding." 37 C.R.F. §1.56 (2004). The Federal Circuit has also held that "[a] reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991)(citing Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991)). In addition, the court notes

that these documents were designated "highly confidential" and were subject to the parties' stipulated protective order. This protective order limited the use of "highly confidential" information to persons or entities "to whom such information is disclosed solely for the purposes of this action, and not for any other action or for any business, patent prosecution, licensing, competitive, or governmental purpose or function, and such information shall not be disclosed to anyone except as provided in this [p]rotective [o]rder." (D.I. 40 at ¶6) The in-house corporate counsel who prosecuted the '536 patent during reexamination (i.e., Mr. Raffle and Mr. Sanjay Bagade), consequently, were not privy to "highly confidential" documents. The court, therefore, reasons that Arthrocare's in-house counsel did not intend to deceive the PTO about Smith & Nephew's summary judgment motions and expert reports because they likely were unaware of the existence of these documents.

As to Arthrocare's "off-the record" conversations with the examiner during the '536 reexamination prior to the first office action,[26] there is no evidence of record to suggest that Arthrocare's in-house counsel violated 37 C.R.F. § 1.56 or MPEP § 2281. Interviews about the patentability of claims involved in an ex parte reexamination proceeding ordinarily are not conducted

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[26]The examiner issued the first office action on September 24, 2002.

prior to the first office action. See 37 C.R.F. § 1.56 (2004); see also MPEP § 2281 (2001). However, interviews are "permitted where the examiner initiates the interview for the purpose of providing an amendment to make the claims patentable and the patent owner's role is passive. The patent owner's role . . . is limited to agreeing with the change or not." Id. Additionally, 37 C.R.F. § 1.56 and MPEP § 2281 require the patent holder to file a written statement of the substance of the interview with the PTO. In accordance with these rules, Mr. Bagade submitted a statement on December 19, 2002 to summarize various communications with the examiner. While the exact number of conversations between Arthrocare's in-house counsel and the examiner and the dates of such conversations are not clear from the contents of Mr. Bagade's statement, it is evident that at least one occurred prior to the first office action because Mr. Bagade stated that the examiner contacted him in May 2002. (See D.I. 462, ex. B at 228-230) This interview, nevertheless, was consistent with the requirements of MPEP § 2281. That is, the examiner contacted Mr. Bagade for purposes of discussing an amendment to claim 1 of the '536 patent, and Mr. Bagade responded by not agreeing to the amendment. (See id.)

Even though the court cannot identify with certainty the time frames for the remaining interviews of record, the court concludes that the record does not suggest that Mr. Raffle caused

the examiner to "parrot back, verbatim" the arguments that he made with respect to the '198 patent during the earlier prosecution of the '592 patent as alleged by Smith & Nephew, despite his discussions with the examiner about the '198 patent, the '667 patent, and Judge Orrick's opinion.[27] Under patent office rules, a patent examiner is charged with a duty to independently conduct a thorough examination.

> On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

37 C.R.F. §1.104(a)(1) (2004). The Federal Circuit "presumes that the Patent Office complies with its own rules, a presumption overcome only upon presentation of contrary evidence." Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1103 (Fed. Cir.)(citing Rite Hite Corp. v. Kelley Co., Inc., 819 F.2d 1120, 1123 (Fed. Cir. 1987)). In line with this duty, the examiner placed his initials next to the '198 patent on the Form PTO-1449, indicating that he considered the patent. The examiner confirmed

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[27]Additional communications of record entailed procedural concerns, such as the status of the reexamination proceedings, filing of information disclosure statements, and an estimate of when the PTO would provide the first office action.

this review in a November 15, 2002 office action, stating that he engaged in "careful[] consideration and review of the Roos '198 patent." (PX 7 at 214) Therefore, without evidence of indiscretion during the '536 reexamination proceeding, the court finds that Smith & Nephew's allegations regarding inequitable conduct based on off-the-record conversations to be without merit. Consequently, the court grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent.

Focusing on the '882 patent, the court finds no evidence in the record to substantiate Smith & Nephew's allegations that Mr. Raffle intentionally misled the PTO when he asserted that he amended all claims to replace the term "active electrode" with "electrode terminal" or when he presented an antecedent basis argument as grounds to amend application claim 23 (i.e., issued claim 1) but did not point out other instances of improper antecedent basis within the claim set. Mr. Raffle filed a supplemental amendment during the prosecution of the '882 patent to change "active electrode" to "electrode terminal" and "electrically conducting liquid" to "electrically conducting

fluid."[28] (See DTX 306 at C2-C12) He missed one correction of "active electrode" in application claim 23 and one instance of the same correction in application claim 52. Recognizing these mistakes after reviewing the '882 patent on the day it issued, Mr. Raffle filed a request for certificate of correction the following day. (See 1527, DTX 306 at C13-C15) In his request, Mr. Raffle explained that he mistakenly forgot to replace the term "active electrode" with "electrode terminal" in one place in application claim 23 and that such failure potentially created an antecedent basis problem. (See DTX 306 at C13) Given this sequence of events, the court concludes that Mr. Raffle made honest mistakes in amending the claims; he did not craft claims to read on Ethicon's products in order to file an infringement action against Ethicon. The court, consequently, grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '882 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '882 patent.

Finally, because the court has not found Arthocare liable for inequitable conduct with respect to any of the individual patents in suit, the court declines to hold them collectively unenforceable based upon an alleged pattern of inequitable

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[28]Mr. Raffle replaced seventeen of the nineteen occurrences of the term "active electrode," including three in application claim 23 and two in application claim 52.

conduct. Even if the court had found just one patent invalid on inequitable conduct grounds, the court is not convinced that Smith & Nephew would be able to show an "immediate and necessary relation" between the inequitable conduct associated with that one patent and the enforcement of the other two patents. To establish the requisite relatedness, Smith & Nephew relies on the fact that the three patents in suit share the same inventors, concern the same electrosurgical system, have been licensed together, and were asserted concurrently in the instant litigation. Nevertheless, this court agrees with the Eastern District of Pennsylvania's holding that "'[m]ere relatedness of subject matter' is insufficient to establish this [immediate and necessary] relationship." Id. (citing Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 810-811 (Fed. Cir. 1990)). In cases where courts found infectious unenforceability, there was greater connection between the act that triggered the inequitable conduct finding and the other patents in suit than in the case at bar. For example, in Consol. Aluminum Corp. 910 F.2d 804, the Federal Circuit held that the intentional fabrication of a fictitious best mode in one patent rendered three other patents with intertwined prosecution histories, two of which were continuations-in-part of the third, unenforceable. The court, therefore, grants Arthrocare's motion for entry of judgment of no inequitable conduct and denies Smith & Nephew's cross motion to

strike Arthrocare's motion for entry of judgment of no inequitable conduct on infectious unenforceability grounds.

**J. Arthrocare's Motion for a Permanent Injunction**

Arthrocare moves for entry of a permanent injunction to enjoin Smith & Nephew from directly infringing, contributing to the infringement, and inducing the infringement of the '536, '592, or '882 patents (1) by making, using, offering to sell, selling, marketing, advertising, or promoting in the United States or importing into the United States all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit; and (2) by instructing, training, or otherwise actively encouraging others in the United States to use all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit. The framers of the Constitution of the United States recognized that a patentee has the right to exclude others from practicing a patented invention. As a result of this belief, the framers adopted Clause 8 of Section 8, Article I which states: "The Congress shall have power . . . to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. art. I, § 8. Congress used their power to enact 35 U.S.C. § 283. This provision of law authorizes a court to "grant injunctions in accordance with the

principles of equity to prevent the violation of any right secured by patent, on such terms as the [c]ourt deems reasonable." 35 U.S.C. § 283.

In a patent infringement suit, a district court may grant a preliminary injunction pending trial or a permanent injunction "after a full determination on the merits." High Tech. Med. Instr., Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1554 (Fed. Cir. 1995). Indeed, the Federal Circuit has indicated that once a finding of infringement has been made, then an injunction should issue absent a sufficient reason for denying it. Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1247 (Fed. Cir. 1989). Courts, therefore, are given wide latitude in framing injunctive relief. KSM Fastening Sys., Inc. v. H.A. Jones Co., 776 F.2d 1522, 1527 (Fed. Cir. 1985). Nonetheless, consistent with the equitable nature of a permanent injunction, the court "must consider all circumstances, including the adequacy of the legal remedy, irreparable injury, whether the public interest would be served, and the hardship on the parties and third parties. E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 659 F. Supp. 92, 94 (D. Del. 1987). Additionally, Rule 65(d) of the Federal Rules of Civil Procedure requires an injunction to "set forth the reasons for its issuance, be specific in its terms, and shall describe in reasonable detail, and not by reference to the complaint or other document, the act

or acts sought to be restrained; and is binding only upon the parties to the action." Fed. R. Civ. P. 65(d).

In the instant case, the court finds Arthocare will suffer irreparable harm without a permanent injunction to prevent Smith & Nephew from practicing its patented inventions. As best stated by the Federal Circuit in H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384 (Fed. Cir. 1987):

> In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement . . . The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the patentee whole, for the principal value of a patent is its statutory right to exclude.

Id. at 390.

Additionally, the public interest in preserving incentives to advance science and useful arts favors entry of an injunction to bar any further infringement by Smith & Nephew. The court recognizes that intellectual property law is premised on the desire to give inventors an incentive to invent and to reap the benefits of their labor. To this end, the Federal Circuit has previously noted that

> [o]ne of those benefits is the right to prevent others from practicing what they have invented. Otherwise, if inventors cannot depend on their patents to exclude others, we fear that research and development budgets in the science and technology based industries would shrink, resulting in the public no longer benefitting from the labors of these talented people.

E.I. DuPont de Nemours v. Polaroid Graphics Imaging, Inc., 706 F. Supp. 1135, 1146 (D. Del. 1989). Under the facts at bar, Arthrocare created the market for electrosurgery probes by launching its first bipolar radio frequency ablation product for arthroscopic surgery in 1995. (See PX 450 at 3) Smith & Nephew later joined this market. (See PX 593 at 24, 39)

Finally, the court notes that removing the Saphyre, ElectroBlade, and Control RF probes from the stream of commerce will not harm or cause hardship to the public since Arthrocare, along with several other suppliers like Mitek and Stryker, offer alternative viable probes. As well, Smith & Nephew has already pulled the Control RF product from the market and only just recently launched the ElectroBlade and Saphyre products. The fact that Smith & Nephew may suffer a loss in revenue is not of concern. Indeed, the Federal Circuit has commented that just because an injunction might put an infringer out of business does not justify denying it. See Windsurfing Int'l, Inc. V. AMF, Inc., 782 F.2d 995, 1003 (Fed. Cir. 1986). "One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Id. Therefore, concluding that all relevant factors weigh in favor of granting a permanent

injunction, the court grants Arthrocare's motion for a permanent injunction.[29]

## V. CONCLUSION

For the reasons stated, the court denies Smith & Nephew's motion for judgment as a matter of law, motion for a new trial, and motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct. The court also denies Smith & Nephew's motion to modify the protective order. The court grants Arthrocare's motion for entry of judgment of no inequitable conduct and motion for entry of a permanent injunction. An order shall issue.

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[29]The court notes that Smith & Nephew's antitrust counterclaims are no longer pending before the court and will not be adjudicated in phase two. The court granted Arthrocare's motion to dismiss Smith & Nephew's antitrust counterclaims in a separately issued memorandum opinion. For this reason, the court concludes that it is not premature to issue a permanent injunction at this time.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| ARTHROCARE CORPORATION, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 01-504-SLR |
| | ) | |
| SMITH & NEPHEW, INC., | ) | |
| | ) | |
| Defendant. | ) | |

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Jack B. Blumenfeld, Esquire, Karen Jacobs Louden, Esquire and James W. Parrett, Jr., Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Matthew D. Powers, Esquire, Jared Bobrow, Esquire and Perry Clark, Esquire of Weil, Gotshal & Manges LLP, Redwood Shores, California.

William J. Marsden, Jr., Esquire and Keith A. Walter, Jr., Esquire of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Mark J. Hebert, Esquire and Kurtis D. MacFerrin, Esquire of Fish & Richardson P.C., Boston, Massachusetts.

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**MEMORANDUM OPINION**

Dated: April 27, 2004
Wilmington, Delaware

ROBINSON, Chief Judge

## I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful direct, contributory, and inducing infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent"). (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (Id.) Smith & Nephew also asserted counterclaims for a declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended its answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219) By order dated November 27, 2002, the court stayed discovery and trial related to the antitrust counterclaims. (D.I. 206)

From April 30, 2003 through May 9, 2003, the

parties tried the issues of infringement and invalidity before a jury. The jury found by a preponderance of the evidence that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of claims 46, 47, and 56 of the '536 patent with its Saphyre, ElectroBlade, and Control RF products. (D.I. 405) The jury also found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 13, 17, and 54 of the '882 patent with its Saphyre, Saphyre with Suction, and Control RF products. (Id.) In addition, the jury found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent with its Saphyre, ElectroBlade, and Control RF products.[1] (Id.) The jury further found that Smith & Nephew did not prove by clear and convincing evidence that the patents in suit are invalid. (Id.)

Following this verdict, the parties filed numerous post-trial motions. Smith & Nephew, in particular, challenged every issue that the jury decided and also nearly every issue that the court decided. The court issued a memorandum opinion and order on March 10, 2004 addressing these motions. (See D.I.

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[1]The jury was not asked to decide whether Smith & Nephew contributed to the infringement or induced the infringement of claims 21 and 42 of the '592 patent with its Saphyre or ElectroBlade products.

483, 484) The court found that the jury based their decisions as to infringement and invalidity upon substantial evidence and upheld the jury verdict. The court granted Arthrocare's motion for a permanent injunction pursuant to the findings of infringement.

Presently before the court are Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction and Smith & Nephew's motion to stay the injunction or, alternatively, to grant a transition period. For the reasons that follow, the court denies the motion for reconsideration, denies the motion to stay in part as to the stay per se, and grants the motion to stay in part to allow for a three month transition period.

## II. DISCUSSION

### A. Smith & Nephew's Motion for Reconsideration of Orders Granting Arthrocare's Motion for a Permanent Injunction[2]

"As a general rule, motions for reconsideration should be granted 'sparingly.'" Stafford v. Noramco of Delaware, Inc., 2001 WL 65738, *1 (D. Del. 2001)(quoting Karr v. Castle, 768 F.

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[2]Because the court dismissed Smith & Nephew's antitrust counterclaim, the court concluded that it was not premature to enter a permanent injunction in favor of Arthrocare. (D.I. 483 at 90, n.29) Thus, Smith & Nephew's instant motion is inextricably tied to the motion to dismiss. The court, therefore, necessarily must address its decision to dismiss the antitrust counterclaims in the context of the instant motion for reconsideration.

Supp. 1087, 1090 (D. Del. 1991)). The purpose of granting a motion for reconsideration is to "correct manifest errors of law or fact or to present newly discovered evidence." Harsco Corp. v. Zlotnicky, 176 F.3d 669, 677 (3d Cir. 1999) (citing Keene Corp. v. International Fid. Ins. Co., 561 F. Supp. 656, 665 (N.D. Ill. 1983)). Parties, therefore, should remain mindful that a motion for reconsideration is not merely an opportunity to "accomplish repetition of arguments that were or should have been presented to the court previously." Karr v. Castle, 768 F. Supp. 1087, 1093 (D. Del. 1991) (citing Brambles U.S.A., Inc. v. Blocker, 735 F. Supp. 1239, 1240-41 (D. Del. 1990)). A court should reconsider a prior decision if it overlooked facts or precedent that reasonably would have altered the result. Id. (citing Weissman v. Fruchtman, 124 F.R.D. 559, 560 (S.D.N.Y. 1989)).

Smith & Nephew complains that the court, in granting Arthrocare's motion to dismiss its antitrust counterclaim, relied on two mistaken assumptions: (1) that Arthrocare's motion to dismiss was unopposed; and (2) that the viability of Smith & Nephew's antitrust counterclaim depends on a showing that the antitrust action was objectively baseless "sham" litigation. Smith & Nephew argues that it did not respond to the motion to dismiss because the court specifically stayed the antitrust counterclaim pending resolution of the patent issues during a teleconference with the parties on June 9, 2003.

As a result, Smith & Nephew asserts that its intent to oppose the motion to dismiss coupled with the court's orders staying the issue presents sufficient grounds for reconsideration.

The court disagrees. As noted above, on November 27, 2002, the court issued a memorandum order staying **discovery** and **trial** of Smith & Nephew's antitrust counterclaim. (D.I. 206) The court reviewed this order in deciding the motion to dismiss and concluded that said stay did not impact the motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). Arthrocare filed this motion in lieu of an answer to Smith & Nephew's antitrust counterclaims. As such, the court simply addressed the sufficiency of Smith & Nephew's counterclaim; it did not resolve disputed facts or decide the merits of Smith & Nephew's antitrust case. Therefore, the court acted consistent with its prior rulings.[3]

More importantly, the court decided said motion based upon the correct law. The court noted in its memorandum opinion that "[t]he Supreme Court has held that Noerr-Pennington immunity does not apply to petitions that are a 'mere sham to cover what is

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[3]Smith & Nephew's reliance on one statement from a June 2003 teleconference is misplaced. The court notes in this regard that the instant docket consists of hundreds of entries, including a dozen transcripts from telephone conferences. The court has had to resolve fifty-one substantive motions in this case, which is only one of sixty-six patent cases on the court's docket. If Smith & Nephew believed that Arthrocare's motion was premature and inconsistent with the court's prior rulings, it should have indicated so in a timely manner.

actually nothing more than an attempt to interfere directly with the business relationships of a competitor.'" (D.I. 481 at 6-7) The court applied this holding and concluded that "the objective threshold for 'sham' litigation is not satisfied and that the Noerr-Pennington doctrine shields Arthrocare from liability for Smith & Nephew's antitrust counterclaims." (Id. at 8) The court is not persuaded that any argument from Smith & Nephew about the basis for its antitrust allegations will change the court's decision. Accordingly, because the court is convinced that it properly decided the motion to dismiss, the court denies Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction.

**B. Smith & Nephew's Motion to Stay the Permanent Injunction Or, Alternatively, to Grant a Transition Period**

Smith & Nephew seeks a stay of the permanent injunction pending appeal to avoid injustice or, in the alternative, a six to twelve month transition period to allow the medical community to switch to alternative products. A court may stay an injunction pending appeal pursuant to Federal Rule of Civil Procedure 62(c). In exercising its discretion to issue such a stay, the Federal Circuit has indicated that a court must consider four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay;

(3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." Standard Havens Prods. v. Gencor Indus., 897 F.2d 511, 512 (Fed. Cir. 1990)(citations omitted). The Federal Circuit also has opined that each factor need not be given equal weight. Id. at 513. Instead, a court should use a flexible balancing approach.

Applying these considerations to Smith & Nephew's assertion that it is entitled to a stay pending appeal, the court finds that Smith & Nephew has not established any of Standard Havens factors sufficient to warrant a stay. First, there is no convincing evidence that Smith & Nephew's appeal carries a strong likelihood of success on the merits. Smith & Nephew argues that the ultimate validity of the asserted patents is in substantial doubt given that the United States Patent & Trademark Office ("PTO") has granted its requests for reexamination of each of the asserted patents, finding "substantial new questions of patentability." A reexamination proceeding, however, is different from litigation. Indeed, the Federal Circuit has recognized that "litigation and reexamination are distinct proceedings, with distinct parties, purposes, procedures, and outcomes."[4] Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427 (Fed.

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[4]The Federal Circuit explained the distinctions between the two proceedings succinctly as follows:

Before the courts, a patent is presumed valid and the

Cir. 1988)(citing In re Etter, 756 F.2d 852, 857 (Fed. Cir. 1985)). To this end, "[t]he two forums take different approaches in determining invalidity and on the same evidence could quite correctly come to different conclusions. . . . And, if the district court determines a patent is not invalid, the PTO should continue its reexamination because, of course, the two forums have different standards of proof for determining validity." Id. at 1428-29. In light of these differences, the court is not persuaded that the ongoing reexamination proceeding triggers a stay of the injunction. A jury has decided the validity of the patents in suit after careful deliberation following a nine day jury trial. This court reviewed the jury's verdict pursuant to post-trial motions and found that the jury based its decision on substantial evidence. Thus, the court has no reason to believe

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> party asserting invalidity must prove the facts to establish invalidity of each claim by clear and convincing evidence.. . . In a reexamination proceeding, on the other hand, there is no presumption of validity and the "focus" of the reexamination returns essentially to that present in an initial examination, . . . at which a preponderance of the evidence must show nonpatentability before the PTO may reject the claims of a patent application.. . . The intent underlying reexamination is to 'start over' in the PTO with respect to the limited examination areas involved, and to re-examine the claims, and to examine new or amended claims, as they would have been considered if they had been originally examined in light of all of the prior art of record in the reexamination proceeding.

Id. (citations and quotations omitted).

that Smith & Nephew will be successful on its appeal such that the court presently should issue a stay.

Smith & Nephew also asserts that there are substantial claim construction issues on appeal that will require further action by the court.[5] Smith & Nephew reminds the court that "the Federal Circuit conducts a de novo review of claim construction, and quite frequently reverses or at least modifies the construction applied by the [d]istrict [c]ourt." (D.I. 487 at 11) Nevertheless, as counsel for Smith & Nephew is aware, the court previously has held that the "possibility of appellate de novo review of its claim construction does not constitute an extraordinary circumstance to merit a stay." Eaton Corp. v. Parker-Hannifin Corp., 292 F. Supp. 2d 555, 582 (D. Del. 2003); see Tristrata Tech., Inc. v. ICN Pharms., Inc., 2004 WL 856595, *2 (D. Del. 2004).

Smith & Nephew further contends that it will appeal the fact that the jury was allowed to decide the validity of the Certificate of Correction for the '882 patent. Smith & Nephew maintains that such procedure was contrary to the steps outlined in Superior Fireplace v. Majestic Prods., 270 F.3d 1358 (Fed. Cir. 2001). Smith & Nephew, therefore, avers that it has a

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[5]Smith & Nephew particularly challenges the court's claim construction of the "not in contact" limitation in the '592 patent and the "connector" limitation of the '536 patent.

reasonable likelihood of succeeding on this claim.[6] This assertion is little more than conclusory attorney argument. Moreover, the court agreed with the jury verdict that the certificate of correction is valid. Therefore, even if it was improper to submit this decision to the jury, the court ultimately decided the very issue at the heart of Smith & Nephew's complaint. Accordingly, the court concludes that the first factor weighs against the issuance of a stay.

Second, Smith & Nephew argues that it will be irreparably harmed if a stay is not granted because it will be unable to recover a position in the market. In this regard, Smith & Nephew claims that its ElectroBlade and Saphyre probes are the result of twenty-seven years and millions of dollars in research and development efforts. This argument is a warmed-over version of Smith & Nephew's prior contentions made in opposition to Arthrocare's motion for a permanent injunction. As the patentee, Arthrocare presumptively has suffered irreparable harm throughout the duration of Smith & Nephew's infringing activities. Smith & Nephew cannot now attempt to turn the table and argue that it will suffer harm for continuing to engage in infringement. Such contention offends the very rights associated with obtaining a patent. Additionally, the only harm that Smith

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[6]Absent a finding of validity of the Certificate of Correction, Smith & Nephew would not be liable for infringement of the '882 patent.

& Nephew will suffer with any certainty is the loss of profits from the sale of its ElectroBlade and Saphyre probes.[7] Smith & Nephew has failed to show that any of its employees will lose their jobs, despite alleging that its employees derive their livelihood from the manufacture and sale of the infringing products. As the court originally stated in deciding the parties' post-trial motions, "one who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 (Fed. Cir. 1986); see also E.I. DuPont De Nemours & Co., v. Phillips Petroleum Co., 659 F. Supp. 92, 94-95 (D. Del. 1987) (stating "the loss of customers or business built upon the sale and use of infringing products does not amount, in the context of a patent infringement suit, to irreparable harm from which [the defendant] should be shielded). The court, consequently, concludes that the second factor weighs against the issuance of a stay.

Third, Smith & Nephew claims that Arthrocare's pattern of licensing demonstrates that monetary damages will adequately compensate Arthrocare for its continued infringement during the

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[7]Smith & Nephew reported revenue of almost two billion in 2003. (D.I. 487 at 16 n.5) From the infringing products alone, Smith & Nephew generated six million in sales before trial and approximately 7.5 million since the jury verdict. (See D.I. 418 at 869; D.I. 491 at 18)

appeals process. This argument is unpersuasive. Staying the injunction during the appeals process would essentially allow Smith & Nephew to continue to infringe, thereby further usurping the exclusivity that Arthrocare is entitled to enjoy as a result of its patents. Such exclusivity underlies the patent system in the United States. Moreover, Arthrocare's patent rights are not compromised simply because it opted to license its patents to select competitors. "Once the patentee's patents have been held to be valid and infringed, he should be entitled to the full enjoyment and protection of his patent rights." Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983).

Furthermore, if Smith & Nephew continues to sell its infringing products, Arthrocare likely will lose market share, profits, and goodwill. Smith & Nephew, in fact, has implemented a specific program within its sales force to convert Arthrocare's customers to using Smith & Nephew products. (See D.I. 491, ex. A) The Federal Circuit has observed that "because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole." Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1456-57(Fed. Cir. 1988). As well, "[i]f monetary relief were the sole relief afforded by the patent statute then injunctions would be unnecessary and infringers could become compulsory licensees for as long as the

litigation lasts." Atlas Powder Co. v. Ireco Chems., 773 F.2d 1230, 1233 (Fed. Cir. 1985). In light of the foregoing, the court concludes that the third factor weighs against the issuance of a stay.

Finally, Smith & Nephew charges that an injunction would adversely affect surgeons and their patients. Smith & Nephew specifically claims that denying a stay will deprive surgeons in the United States of their choice of surgical instruments, especially given that the infringing products offer unique features and medical advantages not available in other products.[8] Nonetheless, the court does not find a stay warranted simply because the litigation at bar involves medical devices as opposed to some other technology that does not relate to issues of human heath.[9] While the court appreciates that select surgeons like Dr. Roy A. Majors and Dr. Gary S. Fanton, both of

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[8]The ElectroBlade combines a mechanical shaver with an RF coagulation device, thereby allowing surgeons to resect soft tissue, coagulate bleeders, and continue resecting with a single instrument. The Saphyre utilizes a CoolBack feature, which prevents contact between the return electrode and non-target tissue.

[9]The court notes that Smith & Nephew attempts to mislead it into believing such to be the case in the District of Delaware by its characterization of C.R. Bard, Inc. v. Medtronic, Inc., 1999 WL 458305 (D. Del. 1999). Smith & Nephew suggests that the court stayed an injunction pending appeal because the technology involved arterial filters. (See D.I. 487 at 17) In truth, the court stayed the injunction because the jury's verdict rested on a close question of law concerning the doctrine of equivalents. Id. at 15.

whom submitted declarations on behalf of Smith & Nephew, rely on the unique features offered by the ElectroBlade and Saphyre products, the court finds that reasonable alternative probes exist in the market. As mentioned previously in the court's post-trial memorandum opinion, ArthroCare, Mitek, and Stryker offer probes for use in arthroscopic surgery. The court has no reason to believe that these probes will pose medical risks to patients. Surgeons in the United States, therefore, may utilize them in place of the ElectroBlade and Saphyre probes, albeit after instruction and training. Consequently, the court finds that the fourth factor weighs against the issuance of a stay.

In sum, since all four of the Stanford Havens factors weigh against the issuance of a stay, the court concludes that a stay pending appeal is not justified. Accordingly, the court denies Smith & Nephew's motion to stay the injunction.

With regard to a transition period, the court disagrees with Smith & Nephew that the medical community may need six to twelve months to effect an efficient and orderly transition. The jury returned its verdict of infringement on May 12, 2003. Smith & Nephew, nevertheless, continued to sell and presently still sells the ElectroBlade and Saphyre probes.[10]

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[10]Smith & Nephew stated that in the past year surgeons treated 50,000 patients at 900 hospitals and surgery centers and 200 sales representative spent approximately $1,100,000 training surgeons and hospital staff to uses its probes. (See D.I. 487 at 17)

Smith & Nephew could have utilized the time between the jury verdict and present to implement the transition it now requests. What is more, a lengthy transition of six to twelve months will cause further irreparable harm to Arthrocare. Notwithstanding this, the court finds that a short transition period of three months is appropriate to allow Smith & Nephew time to alert surgeons not to utilize its probes. This period will also permit the surgeons who rely on Smith & Nephew products to receive instruction and switch to alternative probes. During this time, Smith & Nephew shall not sell any additional infringing probes from its inventory. If Arthrocare becomes aware of such sales by Smith & Nephew, then Arthrocare may immediately notify the court.

**III. CONCLUSION**

The court denies Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction. The court also denies Smith & Nephew's motion to stay in part as to the stay per se and grants said motion in part to allow for a three month transition period. An order shall issue.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| ARTHROCARE CORPORATION, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 01-504-SLR |
| | ) | |
| SMITH & NEPHEW, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**REVISED ORDER***

At Wilmington this 28th day of April, 2004, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction (D.I. 488*) is denied.

2. Smith & Nephew's motion to stay or alternatively, to grant a transition period (D.I. 486) is denied in part as to the stay and granted in part to allow for a three month transition period.

United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| ARTHROCARE CORPORATION, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 01-504-SLR |
| | ) | |
| SMITH & NEPHEW, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**O R D E R**

At Wilmington this 9th day of June, 2004, having conferred with counsel and having reviewed the papers submitted by the parties;[1]

IT IS ORDERED that, with respect to the U.S. Patent No. 5,697,536 ("the '536 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from: (a) directly infringing claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by making, using, offering to sell, or selling in the United States, or importing into the United States, the Saphyre,[2] ElectroBlade, or Control RF

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[1]Arthrocare's motion for entry of a permanent injunction (D.I. 485) is granted, and Smith & Nephew's motion to delay entry of injunction pending consideration of motion to stay injunction in Federal Circuit (D.I. 511) is denied as moot.

[2]When the court refers to the Saphyre products listed on Exhibit A herein, the court intends to include both the suction and non-suction models, unless otherwise specified.

products listed on Exhibit A attached hereto; (b) inducing the infringement of claims 46, 47, and 48 of the '536 patent until the expiration of the '536 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A ; and (c) contributing to the infringement of claims 46, 47, and 48 of the '536 patent until the expiration of the '536 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 5,697,882 ("the '882 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from

inducing the infringement of claim 54 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the suction models of Saphyre products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 17 and 54 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

5. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from

contributing to the infringement of claim 54 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the suction models of the Saphyre products listed on Exhibit A.

6. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 17 and 54 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 6,224,592 ("the '592 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents,

servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 21 and 42 of United States the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 21 and 42 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that:

1. Defendant Smith & Nephew retrieve from all persons and

entities, including sales representatives, distributors, executives, doctors, and hospitals, all Saphyre, ElectroBlade, and Control RF products listed in Exhibit A for which title has not passed from Smith & Nephew, Inc..

2. Defendant Smith & Nephew provide a copy of this order to each of its sales representatives, distribution executives, and other distributors for the Saphyre, ElectroBlade, and Control RF products listed in Exhibit A, whether or not such persons are employees of Smith & Nephew, Inc..

3. Defendant Smith & Nephew shall have a transition period from the date of this order until July 27, 2004[3] to allow time for defendant Smith & Nephew to alert surgeons not to utilize the Saphyre, ElectroBlade, and Control RF probes listed on Exhibit A and for surgeons to receive instruction on alternative, non-infringing products.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined committing any of the acts enumerated herein during this transition period.

United States District Judge

[3]The court granted Smith & Nephew a three month transition period commencing on April 27, 2004. (See D.I. 508) This transition period concludes on July 27, 2004.

## Exhibit A

## The Infringing Products

### I. Saphyre Products

Saphyre 90-degree, 3 mm Bipolar Ablation Probe, Integrated Cable, REF 925001 / 7209686

Saphyre 90-degree, 3 mm Suction Bipolar Ablation Probe, Integrated Cable, REF 925011 / 7209683

Saphyre 60-degree, 3 mm Bipolar Ablation Probe, Integrated Cable, REF 925003 / 7209685

Saphyre 60-degree, 3 mm Suction Bipolar Ablation Probe, Integrated Cable, REF 925013 / 7209682

Saphyre 90-degree HP Ablator, REF 7209684

Saphyre 90-degree HP Ablator with suction, REF 7209681

Pro-Saphyre 60-degree Small Joint with Suction, Oratec No. 925016

Pro-Saphyre 60-degree Small Joint, Oratec No. 925026

Saphyre II 90-degree HP with Suction, REF 7210112

Saphyre II 90-degree with Suction, REF 7210111

Saphyre II 60-degree with Suction, REF 7210113

Saphyre II 40-degree curved with Suction, REF 7210185

### II. ElectroBlade Products

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius Blade, REF 7205961

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite, REF 7209700

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Full Radius Vulcan Plug-in, REF 7205962

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Elite Vulcan Plug-in, REF 7209982

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius Blade Vulcan Plug-in, REF 7209855

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite Vulcan Plug-in, REF 7209983

**III. Control RF Products**

Dyonics Series 7000 RF Arthroscopic Probe, Type RS, REF 7205956

Dyonics Series 7000 RF Arthroscopic Probe, Type RSX, REF 7205957

Dyonics Series 7000 RF Arthroscopic Probe, Type RE, REF 7209034

Dyonics Series 7000 RF Arthroscopic Probe, Type REX, REF 7209035

Dyonics Series 7000 RF Arthroscopic Probe, Type AP, REF 7209036

Dyonics Series 7000 RF Arthroscopic Probe, Type APX, REF 7209037

Dyonics Series 7000 RF Arthroscopic Probe, Type MR, REF 7209038

Dyonics Series 7000 RF Arthroscopic Probe, Type MRX, REF 7209039

Dyonics Control RF Generator Adaptor, REF 7207908

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| ARTHROCARE CORPORATION, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 01-504-SLR |
| | ) | |
| SMITH & NEPHEW, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**AMENDED ORDER**

At Wilmington this 24th day of June, 2004, having conferred with counsel and having reviewed the papers submitted by the parties;[1]

Upon entry, this Amended Order shall replace and supercede the Order entered by this Court on June 9, 2004 (D.I. 522):

IT IS ORDERED that, with respect to the U.S. Patent No. 5,697,536 ("the '536 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from: (a) directly infringing claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by making, using, offering to sell, or selling in the United States, or importing

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[1]Arthrocare's motion for entry of a permanent injunction (D.I. 485) is granted, and Smith & Nephew's motion to delay entry of injunction pending consideration of motion to stay injunction in Federal Circuit (D.I. 511) is denied as moot.

into the United States, the Saphyre,[2] ElectroBlade, or Control RF products listed on Exhibit A attached hereto; (b) inducing the infringement of claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A ; and (c) contributing to the infringement of claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 5,697,882 ("the '882 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

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[2]When the court refers to the Saphyre products listed on Exhibit A herein, the court intends to include both the suction and non-suction models, unless otherwise specified.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13, 17, and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the suction models of Saphyre products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 17 and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the non-suction models of the Saphyre products

listed on Exhibit A.

5. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13, 17, and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the suction models of the Saphyre products listed on Exhibit A.

6. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 17 and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 6,224,592 ("the '592 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by

inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 21 and 42 of the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 21 and 42 of the '592

patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that:

1. Defendant Smith & Nephew retrieve from all persons and entities, including sales representatives, distributors, executives, doctors, and hospitals, all Saphyre, ElectroBlade, and Control RF products listed in Exhibit A for which title has not passed from Smith & Nephew, Inc.

2. Defendant Smith & Nephew provide a copy of this order to each of its sales representatives, distribution executives, and other distributors for the Saphyre, ElectroBlade, and Control RF products listed in Exhibit A, whether or not such persons are employees of Smith & Nephew, Inc.

3. Defendant Smith & Nephew shall have a transition period from the date of this order until July 27, 2004[3] to allow time for defendant Smith & Nephew to alert surgeons not to utilize the Saphyre, ElectroBlade, and Control RF probes listed on Exhibit A and for surgeons to receive instruction on alternative, non-infringing products.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active

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[3]The court granted Smith & Nephew a three month transition period commencing on April 27, 2004. (See D.I. 508) This transition period concludes on July 27, 2004.

concert or participation with any of them, are enjoined from committing any of the acts enumerated herein during this transition period.

United States District Judge

## Exhibit A

## The Infringing Products

### I. Saphyre Products

Saphyre 90-degree, 3 mm Bipolar Ablation Probe, Integrated Cable, REF 925001 / 7209686

Saphyre 90-degree, 3 mm Suction Bipolar Ablation Probe, Integrated Cable, REF 925011 / 7209683

Saphyre 60-degree, 3 mm Bipolar Ablation Probe, Integrated Cable, REF 925003 / 7209685

Saphyre 60-degree, 3 mm Suction Bipolar Ablation Probe, Integrated Cable, REF 925013 / 7209682

Saphyre 90-degree HP Ablator, REF 7209684

Saphyre 90-degree HP Ablator with suction, REF 7209681

Pro-Saphyre 60-degree Small Joint with Suction, Oratec No. 925016

Pro-Saphyre 60-degree Small Joint, Oratec No. 925026

Saphyre II 90-degree HP with Suction, REF 7210112

Saphyre II 90-degree with Suction, REF 7210111

Saphyre II 60-degree with Suction, REF 7210113

Saphyre II 40-degree curved with Suction, REF 7210185

### II. ElectroBlade Products

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius Blade, REF 7205961

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite, REF 7209700

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Full Radius Vulcan Plug-in, REF 7205962

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Elite Vulcan Plug-in, REF 7209982

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius Blade Vulcan Plug-in, REF 7209855

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite Vulcan Plug-in, REF 7209983

**III. Control RF Products**

Dyonics Series 7000 RF Arthroscopic Probe, Type RS, REF 7205956

Dyonics Series 7000 RF Arthroscopic Probe, Type RSX, REF 7205957

Dyonics Series 7000 RF Arthroscopic Probe, Type RE, REF 7209034

Dyonics Series 7000 RF Arthroscopic Probe, Type REX, REF 7209035

Dyonics Series 7000 RF Arthroscopic Probe, Type AP, REF 7209036

Dyonics Series 7000 RF Arthroscopic Probe, Type APX, REF 7209037

Dyonics Series 7000 RF Arthroscopic Probe, Type MR, REF 7209038

Dyonics Series 7000 RF Arthroscopic Probe, Type MRX, REF 7209039

Dyonics Control RF Generator Adaptor, REF 7207908

# United States Court of Appeals for the Federal Circuit

04-1323, -1487

ARTHROCARE CORPORATION,

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

Jared Bobrow, Weil, Gotshal & Manges LLP, of Redwood Shores, California, argued for plaintiff/counterclaim defendant-appellee. With him on the brief were Matthew D. Powers and Perry R. Clark. Of counsel on the brief were Timothy E. DeMasi, of New York, New York; and Jack B. Blumenfeld and Karen Jacobs Louden, Morris, Nichols, Arsht & Tunnell, of Wilmington, Delaware.

George F. Pappas, Venable LLP, of Washington, DC, argued for counterclaim defendant-appellee. With him on the brief were Vicki Margolis and Rebecca G. Lombard.

Ruffin B. Cordell, Fish & Richardson P.C., of Washington, DC, argued for defendant/counterclaimant-appellant. With him on the brief were Lauren A. Degnan and Tina M. Chappell. Of counsel on the brief were Mark J. Hebert and Thomas M. Johnston, of Boston, Massachusetts. Of counsel was William J. Marsden, Jr., of Wilmington, Delaware.

Appealed from: United States District Court for the District of Delaware

Chief Judge Sue L. Robinson

# United States Court of Appeals for the Federal Circuit

04-1323, -1487

ARTHROCARE CORPORATION

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

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DECIDED: May 10, 2005

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Before MAYER, LOURIE, and BRYSON, Circuit Judges.

BRYSON, Circuit Judge.

The term electrosurgery refers to a surgical technique in which high frequency electrical current is applied to cut or ablate body tissue. There are two forms of electrosurgical devices, monopolar and bipolar. In monopolar devices, electric current passes from a single exposed electrode into the body tissue that is to be ablated. The current then passes through the body to a return electrode, usually attached to the outside of the patient's body. In bipolar devices, both electrodes are inserted into the

body. The current passes from one electrode, through the targeted body tissue, and then back to the return electrode.

Electrosurgery has the benefit of reducing patient bleeding and trauma. However, there are disadvantages to applying high voltages within the patient's body, including the risk that the electrical discharge will cause damage other than to the target tissue. For that reason, the path of the electrical current through the body needs to be carefully controlled. Moreover, surgeons prefer to cleanse the surgical area during arthroscopic procedures with fluids that conduct electricity, such as saline. Therefore, electrosurgical devices need to be usable in such fluids. The patents at issue in this case sought to address the problems of controlling the electrical path and enabling electrosurgical instruments to function in the presence of conductive fluids.

The three patents at issue, U.S. Patent Nos. 5,697,536 ("the '536 patent"), 5,697,882 ("the '882 patent"), and 6,224,592 ("the '592 patent"), are owned by ArthroCare Corporation. ArthroCare sued Smith & Nephew, Inc., in the United States District Court for the District of Delaware claiming that Smith & Nephew was liable for infringement of those patents based on its manufacture of certain electrosurgical probes and the use of those probes in surgery. In response, Smith & Nephew filed a counterclaim alleging that ArthroCare and Ethicon, Inc., had violated the antitrust laws by entering into a conspiracy in restraint of trade. Smith & Nephew's theory of antitrust liability was that ArthroCare and Ethicon had settled an earlier dispute in a manner designed to restrain other competitors from entering the market for electrosurgical devices and that ArthoCare had brought this action, although knowing it to be

objectively baseless, as part of an unlawful conspiracy with Ethicon to interfere with Smith & Nephew's business.

Before trial, the district court bifurcated the case. The first phase encompassed the patent issues of infringement, invalidity, and inequitable conduct. The second phase addressed damages, willfulness, and the antitrust counterclaim. The court stayed the second phase until after completion of the trial on the first.

At the conclusion of the patent trial, the jury determined that Smith & Nephew had directly or indirectly infringed the three patents and that none of the patents were invalid. Smith & Nephew then moved for judgment as a matter of law and a new trial. ArthroCare meanwhile moved to dismiss Smith & Nephew's antitrust counterclaim for failure to state a claim upon which relief could be granted. Before Smith & Nephew's response to that motion was due, the district judge stayed all proceedings on the antitrust counterclaim while she considered Smith & Nephew's motions for judgment as a matter of law and a new trial. The court eventually denied Smith & Nephew's motions and entered a permanent injunction against Smith & Nephew. ArthroCare Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 681 (D. Del. 2004). On the same day, the court granted ArthroCare's motion to dismiss the antitrust counterclaim before Smith & Nephew responded to the motion. Smith & Nephew sought reconsideration of the dismissal order, but the court denied the motion for reconsideration. ArthroCare Corp. v. Smith & Nephew, Inc., 315 F. Supp. 2d 615, 618 (D. Del. 2004). In denying reconsideration, the court stated that the order staying proceedings on the antitrust counterclaim had stayed only discovery and trial of the counterclaim and did not affect the motion to dismiss. The court further stated that Smith & Nephew's reliance on a

statement by the court in a June 2003 telephone conference was misplaced, and that if Smith & Nephew "believed that ArthroCare's motion [to dismiss] was premature and inconsistent with" the court's stay order, it should have indicated so, presumably in a more formal manner. Id. at 318 n.3. The court added that it was "not persuaded that any argument from Smith & Nephew about the basis for its antitrust allegations will change the court's decision." Id. at 319.

I

On appeal, Smith & Nephew first argues that the district court erred in dismissing the antitrust counterclaim without giving it an opportunity to respond to the motion to dismiss or to amend its counterclaim. Following the trial on the patent issues, the district court continued the stay of the antitrust proceedings pending the disposition of Smith & Nephew's motions for judgment as a matter of law and a new trial, and ArthroCare's request for an injunction. After the court ruled on those matters, however, the court dismissed the antitrust counterclaim even though it had not received a response to the motion to dismiss from Smith & Nephew. The court noted that Smith & Nephew had not filed a response to the motion and from its silence "presume[d] that Smith & Nephew does not oppose the motion." Moreover, the court concluded that the "sham litigation" aspect of Smith & Nephew's antitrust counterclaim was baseless. The court did not address the other ground for the antitrust counterclaim, namely, the allegation that ArthroCare and Ethicon had entered into a settlement of their dispute that was designed to exclude other competitors, including Smith & Nephew, from the relevant market.

Smith & Nephew contends that, because of the stay of proceedings on the antitrust counterclaim, it never had an opportunity to respond to the motion to dismiss. In the absence of an opportunity to respond, Smith & Nephew contends that it was error for the court to grant the motion to dismiss.

In its opinion on reconsideration, the district court characterized the pretrial order staying proceedings on the antitrust counterclaim as staying discovery and trial but not the motion to dismiss. While it is true that the written stay order referred only to discovery and trial, the court elaborated on that order in a June 9, 2003, telephone conference, in which the court stated that proceedings on the pending motion to dismiss the antitrust counterclaim were stayed. In response to a question about the pending motion to dismiss, the court stated that "everything is stayed and we'll deal with the antitrust issues later. . . . So the pending motion [to dismiss] on antitrust is stayed and everything having to do with the antitrust counterclaims, discovery, substantive motions, et cetera, is stayed pending further order of the court." In light of that colloquy, it was reasonable for Smith & Nephew to conclude that the stay order extended to the proceedings on the motion to dismiss and that it would not be required to respond to the dismissal motion until the stay was lifted. Thus, the effect of this sequence of events was that the court granted ArthroCare's motion to dismiss the antitrust counterclaim without giving Smith & Nephew an opportunity to respond to the motion.

The Supreme Court has stated that under Rule 12(b)(6) of the Federal Rules of Civil Procedure, "a plaintiff with an arguable claim is ordinarily accorded notice of a pending motion to dismiss for failure to state a claim and an opportunity to amend the complaint before the motion is ruled upon." Neitzke v. Williams, 490 U.S. 319, 329

(1989). The purpose of such a procedure is to enable the plaintiff "meaningfully to respond by opposing the motion to dismiss on legal grounds or by clarifying his factual allegations so as to conform with the requirements of a valid legal cause of action." Id. at 329-30. Providing the plaintiff with an opportunity to respond "crystallizes the pertinent issues and facilitates appellate review of a trial court dismissal by creating a more complete record of the case." Id. at 330.

The Third Circuit, whose law applies to this procedural issue, has extended that principle by adopting a categorical rule that "a Rule 12(b)(6) motion for dismissal . . . may be disposed of only after a hearing, which affords an opportunity to present legal arguments either orally, in writing, or both at the District Court's discretion." Dougherty v. Harper's Magazine Co., 537 F.2d 758, 761 (3d Cir. 1976); see also Oatess v. Sobolevitch, 914 F.2d 428, 430 n.5 (3d Cir. 1990) (a district court may not dismiss a complaint under Rule 12(b)(6) sua sponte without giving the plaintiff a chance to respond). In this case, Smith & Nephew did not have an opportunity to respond to the motion to dismiss, in contravention of that rule.

ArthroCare and Ethicon claim that Smith & Nephew was given the opportunity to contest the motion to dismiss in the form of its motion for reconsideration, which the district court denied. That argument is flawed for several reasons. In Dougherty, the plaintiff also petitioned the district court for reconsideration, yet the Third Circuit reversed the district court for dismissing the case without giving the plaintiff an opportunity to respond. 537 F.2d at 761; see also Jordan v. County of Montgomery, Pa., 404 F.2d 747, 748 (3d Cir. 1969) (finding that "the district court erred in dismissing [the plaintiff's] complaint on the defendants' motions without affording him an

opportunity to submit a written statement in opposition to the motions" even though the plaintiff made a motion for relief from judgment under Rule 60(b)(1)). Additionally, when it denied Smith & Nephew's motion for reconsideration, the district court did not conduct a de novo analysis of the motion to dismiss, but instead applied the highly restrictive standard applicable to reconsideration motions. See ArthroCare, 315 F. Supp. 2d at 618. The reconsideration process thus did not satisfy the requirement that Smith & Nephew be given the opportunity "meaningfully to respond" to the motion to dismiss.

On the merits, ArthroCare and Ethicon argue that Smith & Nephew's counterclaim should fail because the claim does not describe the antitrust injury sufficiently and does not provide enough specificity in describing the antitrust violation. Third Circuit precedent indicates, however, that if a claim fails for lack of specificity, the district court should grant leave to amend the complaint, regardless of whether the complainant asks for it. Shane v. Fauver, 213 F.3d 113, 116 (3d Cir. 2000); Borelli v. City of Reading, 532 F.2d 950, 951 n.1 (3d Cir. 1976). The court should dismiss only if the complainant is unable or unwilling to amend the complaint. Dist. Counsel 47 v. Bradley, 795 F.2d 310, 316 (3d Cir. 1986). We therefore vacate the district court's dismissal of the antitrust counterclaim and direct the court to allow Smith & Nephew to respond to the motion to dismiss. If the court concludes, as urged by ArthroCare and Ethicon, that Smith & Nephew's antitrust counterclaim fails for lack of specificity, Smith & Nephew should be given the opportunity to amend.

Because we dispose of the counterclaim issue on a procedural ground, we take no position on the merits of the counterclaim. However, we note that the district court did not intend to issue a permanent injunction until after it disposed of the antitrust

counterclaim. Because the district court must reconsider that counterclaim on remand, the permanent injunction against Smith & Nephew must be vacated pending the disposition of the antitrust counterclaim. See Tegal Corp. v. Tokyo Electron Am., Inc., 257 F.3d 1331, 1351 (Fed. Cir. 2001).

II

Smith & Nephew next appeals the denial of its motion for judgment as a matter of law that the asserted claims of the '536 patent (claims 46, 47, and 56) were anticipated by a prior art patent, U.S. Patent No. 4,116,198 ("the Roos patent" or "the '198 patent"), and an article by the inventor of that patent, Eberhard Roos and a co-author, E. Elsässer.

As an initial matter, ArthroCare argues that Smith & Nephew is precluded from arguing invalidity on appeal. ArthroCare maintains that Smith & Nephew did not specify the basis on which it sought judgment as a matter of law after presenting its evidence at trial, as required by Rule 50 of the Federal Rules of Civil Procedure. Because of that failure, ArthroCare claims that Smith & Nephew may not assert invalidity now. That argument has no merit, however, because the district judge acknowledged that she precluded argument on the motions for judgment as a matter of law at trial and indicated that Smith & Nephew's rights were preserved.

On the merits, the '536 patent is directed to an electrosurgical system. The three asserted claims of the '536 patent all recite an electrosurgical probe "comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply." The claims also recite "an

electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal." ArthroCare maintains that neither the Roos patent nor the Roos and Elsässer article teaches either an electrically conducting fluid or an electrosurgical probe with a connector at the proximal end connecting the probe to the power supply. We disagree and hold that the evidence at trial clearly established that the prior art references disclose both of those features.

A

With respect to the "electrically conductive fluid" limitation, claim 1 of the Roos patent recites that the claimed electrode is "adapted to be filled with liquid to provide electrical conductance." '198 patent, col. 7, ll. 60-62. ArthroCare posits that there is a legally tenable distinction between a fluid that provides electrical conductance and "an electrically conducting fluid." In particular, ArthroCare argues that while all materials provide some electrical conductance, most do not possess a sufficiently high level of conductivity for a person of skill in the art to consider them "electrically conductive."

ArthroCare's distinction is belied by the description of "electrically conducting fluid" in the '536 patent and by the prosecution history of the Roos patent, which together make clear that both patents recite a fluid that provides a path for the electrical current between the electrodes of the electrosurgical devices. The '536 patent explains that the conducting fluid provides a "current flow path between the target site and the return electrode." '536 patent, col. 3, ll. 27-30; id., col. 7, ll. 35-46. The inventor of the '536 patent affirmed that he used the term "conducting fluid" in the '536 patent to indicate that the fluid "provides the pathway between the active electrode or electrodes,

plural, and the return electrode." Furthermore, the description of the fluid in the patent indicates that the conducting fluid facilitates the passage of current by providing a low electrical impedance current path between the two electrodes. Id., col. 7, ll. 40-43.

The prosecution history of the Roos patent makes clear that the fluid "provid[ing] electrical conductance" recited in claim 1 of the Roos patent reads on the "electrically conducting fluid" of the '536 patent. The Roos patent prosecution history notes that the washing fluid recited in claim 1 of the Roos patent must "provide the necessary electrical conductor" between the electrodes and that "there is always a well-defined current path . . . through the washing (and tissue) fluid." Thus, the Roos patent describes a fluid that creates a "current flow path." That description of the fluid makes sense given the language of claim 1 of the Roos patent, which recites that the liquid "provides electrical conductance between said electrodes." That language means that the fluid is introduced during electrosurgery to provide conductance and to help generate a "current flow path." While it is true that, given enough voltage, an electrical current can be made to flow through any substance, it would be bizarre to say that a non-conductor was introduced to "provide electrical conductance." Consequently, we conclude that the Roos patent discloses an electrically conducting fluid.

The district court provided three reasons for concluding that the Roos patent does not teach an electrically conducting fluid. First, the court reasoned that the Roos patent does not disclose such a fluid because it does not list either saline or Ringer's lactate as an example of an electrically conducting fluid. That rationale is unconvincing, however, because there is no requirement that an anticipating reference must provide specific examples; rather, the reference need only "be enabling and describe the

applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention." In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994). Second, the district court focused on the fact that the Roos patent specification does not distinguish between the fluid used in monopolar devices and the fluid used in bipolar devices. The court reasoned that because most monopolar devices use nonconducting fluid, the Roos patent does not clearly teach conducting fluid. That inference, however, is contradicted by the claim language and prosecution history of the Roos patent reviewed above. Finally, the court looked to an embodiment described in the Roos patent in which the probe touches the tissue. The court concluded that there would be no need for electrical contact with the patient's tissue if the fluid were conducting. The court's analysis, however, focused on only one embodiment in the Roos patent. There are other embodiments in the patent as to which it is clear that no such direct contact is necessary, see, e.g., '198 patent, col. 3, ll. 9-15, and it was error for the district court to limit the disclosure of the prior art reference to a preferred embodiment. See Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc., 127 F.3d 1065, 1068 (Fed. Cir. 1997). ArthroCare makes a similar point, contending that another embodiment described in the Roos patent uses non-conducting fluid. In support of its argument, ArthroCare points to a later patent by Roos, which describes the foreign patent to which the Roos patent claimed priority. Like the district court's analysis, however, ArthroCare's argument fails because it addresses only a single embodiment in the Roos patent.

The Roos and Elsässer article also teaches an electrically conducting fluid. The article describes how problems with prior art monopolar devices can be eliminated by

providing "the high-frequency current a path . . . offering such low resistance that aberrant currents or leakage currents do not even occur." The article describes a way of accomplishing that goal by placing a neutral electrode close to the active electrode in an irrigation liquid so that current flows through the liquid. The article states that creating such a current path with the irrigation liquid creates "very good electrical conditions." Furthermore, the diagrams in the Roos and Elsässer article depict current "directly flowing" along a path through the fluid. The description of the role of the irrigation liquid is quite similar to the description of the role of the conducting fluid in the '536 patent, which is to provide a "current flow path between the target site and the return electrode." '536 patent, col. 3, ll. 27-30.

ArthroCare maintains that the article does not teach an electrically conducting fluid because the article uses the term "irrigation liquid" in describing the liquid used in both the bipolar and the monopolar procedures. As we have noted, most monopolar procedures use nonconducting fluids. Because the article does not use different names for the liquids used in the two procedures, ArthroCare contends that there is no way of knowing if the irrigation liquid is a conducting fluid. ArthroCare's argument fails, however, because the article pays little attention to the nature of the irrigation liquid used in the monopolar prior art. It is unclear whether the liquid in the monopolar procedure is nonconductive or whether it is even the same liquid that is used in the bipolar case. What is clear is that, in describing bipolar devices, the Roos and Elsässer article describes the liquid as providing a path for the current, thus serving as a conducting fluid. Even giving ArthroCare the benefit of all reasonable inferences, the

fact that the article uses the same term to refer to the fluid in both procedures does not justify an inference that the fluid described in the bipolar procedure is nonconductive.

B

ArthroCare also maintains that the Roos patent and the Roos and Elsässer article do not disclose "a connector near the proximal end of the shaft for electrically coupling the electrode terminal to the electrosurgical power supply." Both the patent and the article clearly show that the electrodes are coupled to a power source. See, e.g., '198 patent, col. 5, ll. 30-35. Hence, in arguing that the prior art does not anticipate, ArthroCare focuses on the term "connector near the proximal end." However, both the Roos patent and the article disclose such a connector.

The Roos patent states that the claimed invention relates to an electrosurgical device with electrodes and "an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator." '198 patent, col. 1, ll. 5-15; see also id., col. 7, ll. 50-51. The district court construed the term "connector" to mean "a structure that electrically links the electrode terminal to the high frequency power supply." The insulated cable in the Roos patent does exactly that. Specifically, Figure 4 of the Roos patent provides a schematic diagram for the electrosurgical probes in the patent, and it illustrates that the electrodes are connected via "output lines" to a high frequency generator. See id., col. 5, ll. 8-9; id., col. 5, ll. 35-36.

On appeal, ArthroCare appears to accept the district court's construction of the term "connector," but it asserts that the jury could have rejected the contention that a wire is a connector for the purposes of the '536 patent. ArthroCare raises various

arguments concerning whether a wire is a connector, but those arguments miss the point. The district court stated that a connector is a "structure" that electrically links the electrodes and the power supply. That construction of the term "connector" easily encompasses a wire between the electrodes and the power supply. Because ArthroCare does not dispute the district court's construction, ArthroCare's attempt to distinguish "wires" from "connectors" fails. The Roos patent clearly depicts a connector under the district court's construction.

Furthermore, the Roos patent indicates that the electrical wires that connect the electrodes to the power source pass through the probe. The specification of the Roos patent describes one embodiment as having the two electrical leads to the electrodes "pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of the endoscope 13." '198 patent, col. 7, ll. 3-5. In other words, the electrical leads attach to the power source from near the proximal end of the endoscope. While Smith & Nephew's expert agreed that the Roos patent does not explicitly identify the point at which the wires exit the probe, he stated that a person of skill in the art would understand that the wires would be attached to the power source after exiting the back end of the probe. See Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1347 (Fed. Cir. 2000) (even if a piece of prior art does not expressly disclose a limitation, it anticipates if a person of ordinary skill in the art would understand the prior art to disclose the limitation and could combine the prior art description with his own knowledge to make the claimed invention).

A "connector near the proximal end" of the electrosurgical probe is also found in the Roos and Elsässer article. In Figure 8 of the article, the electrosurgical probe is

drawn in cross-section. The figure shows the active and neutral probes attached to wires, and the labels state that those wires go to the power supply. Therefore, a connector is disclosed in the Roos and Elsässer article as well. Moreover, Figure 10 of the article illustrates how those wires leave the probe. That figure is a schematic diagram, which depicts the cutting and neutral electrodes inside the body and projecting from the "resectoscope shaft" on one end. The wires also project from the other end of the shaft, where they connect to a high frequency power source. Thus, the connectors are shown exiting near the proximal end of the probe. The article even provides a photograph of the instrument depicted in Figure 10. The photograph verifies that the electrical leads leave the probe at its back end. In contending that the article does not disclose a connector near the proximal end of the probe, ArthroCare limits its argument to contesting the veracity of Smith & Nephew's expert and disputing his conclusions regarding the presence of the electrical connector in the article. However, the article speaks for itself, and it clearly discloses such a connector.

In sum, Smith & Nephew has proved by clear and convincing evidence that the asserted claims of the '536 patent were anticipated either by the Roos patent or the Roos and Elsässer article. Because the jury's determination that the '536 patent was not invalid is not supported by substantial evidence, we reverse the district court's denial of Smith & Nephew's motion for judgment as a matter of law on that issue.

III

Smith & Nephew also appeals the denial of its motion for judgment as a matter of law that the '882 patent is invalid because the claims of that patent were impermissibly broadened by a certificate of correction. In particular, Smith & Nephew argues that

claim 1 of the '882 patent required three electrodes when it was originally issued, but that after the correction the claim required only two electrodes. Smith & Nephew contends that the change impermissibly broadened the patent's scope.

When ArthroCare originally filed the application that matured into the '882 patent, the claims recited only an "active electrode" and a "return electrode." Before any examination on the merits, ArthroCare changed the claims by making what it termed "a few minor amendments." Those amendments changed the term "active electrode" to "electrode terminal" in three places in claim 1 of the application, but did not make the change in a fourth place, where the term "active electrode" was left unchanged. The prosecuting attorney noted the error on the same day that the patent issued and immediately asked the Patent and Trademark Office to change the remaining reference from "active electrode" to "electrode terminal." The prosecuting attorney testified at trial that the change listed in the certificate of correction was made solely due to a typographical error. Smith & Nephew did not attempt to rebut that evidence.

The correction of a ministerial error in the claims, which also serves to broaden the claims, is allowable if it is "clearly evident from the specifications, drawings, and prosecution history how the error should appropriately be corrected" to one of skill in the art. Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1373 (Fed. Cir. 2001). At trial, Smith & Nephew sought to show that the requisite standard was not met in the case of the correction to the '882 patent. Smith & Nephew's proof on that issue failed to satisfy the jury, and we hold that substantial evidence supports the verdict.

In the first place, claim 1 of the '882 patent does not make sense if it is interpreted to contain three types of electrodes instead of two. The claim requires that

an electrode terminal and a return electrode be coupled to a high voltage source. The claim as originally issued then required that an "active electrode" be placed in close proximity to the target site. High frequency voltage is then applied between the electrode terminal and the return electrode, which induces the discharge of energy to the target site. Nothing in the patent suggests any reason to place a third type of electrode close to the target site. The whole point of the patent is to use the electrode terminal and return electrode to apply a voltage across the tissue; a third type of electrode would serve no apparent purpose. Moreover, the specification refers to "electrode terminal" and "active electrode" interchangeably. See '882 patent, col. 20, ll. 19-21; id., col. 20, ll. 53-54. That evidence indicates that it was clear how the typographical error in the original claims should have been corrected.

The prosecution history further supports ArthroCare's argument that it was unambiguous how the remaining reference to an active electrode in claim 1 should be changed. From the beginning, the claims referred to only two electrodes. The change of the term "active electrode" to "electrode terminal" was made before any examination on the merits, and the uncontroverted evidence establishes that it was meant to be a global renaming. In fact, most of the references to "active electrode" in the claims were changed. Finally, ArthroCare presented unrefuted testimony from an expert who stated that he understood the term "active electrode" in the uncorrected claim to refer to the "electrode terminal."

Smith & Nephew's only evidence that it remained unclear how to fix the error in claim 1 is that claim 53, which depends on claim 1, also refers to "the active electrode." According to Smith & Nephew, that evidence implies that it cannot be apparent how to

fix the remaining instance of "active electrode" in claim 1, because changing it to "electrode terminal" would leave claim 53 without an antecedent basis. In fact, however, a simple explanation for the use of the term "active electrode" in claim 53 is that the prosecuting attorney made another error in claim 53 of the same type that was corrected in claim 1. The prosecuting attorney's failure to replace the term "active electrode" twice in the claims, instead of once, does not demonstrate by clear and convincing evidence that a person of ordinary skill in the art would not understand how to correct those errors. Accordingly, substantial evidence supports the jury's conclusion that the certificate of correction was valid. We therefore affirm the district court's denial of judgment as a matter of law of invalidity of the '882 patent.

IV

Finally, Smith & Nephew appeals the denial of its motion for judgment as a matter of law that it was not liable for indirect infringement of the '592 patent. The '592 patent pertains to a method for conducting electrosurgery. The method comprises positioning an electrode terminal near the target site in the presence of an electrically conductive fluid. Next, a return electrode is positioned in the fluid, while ensuring "that the return electrode is not in contact with the body structure." '592 patent, col. 24, ll. 13-14. Finally, high frequency voltage is applied between the electrode terminal and the return terminal so as to force current to flow into the target site. Smith & Nephew argues that it is not liable for contributory infringement or inducement of infringement of the '592 patent, because there was no evidence that its probes were ever used in a manner that directly infringed the patented method. Smith & Nephew maintains that none of the videotaped surgical procedures using its probes infringed the patented

method because in every case the return electrode was shown touching "the body structure." Smith & Nephew asserts that the jury erred in finding infringement because ArthroCare convinced the jury to disregard the district court's claim construction.

In construing the claims of the '592 patent, the district court instructed the jury that the return electrode "is not to contact the body at all during the performance of the claimed method." The court noted, however, that "[t]he claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed." Smith & Nephew does not challenge that claim construction.

Based upon the district court's claim construction, the jury was free to find infringement if it concluded that the return electrode did not touch the body when each step of the patented method was being performed. There was no need for the electrode to be kept apart from the body throughout the entire surgical procedure; nothing in the claim language or in the court's claim construction required that the electrode not touch the body at any time between the performance of the steps of the claimed process. That is in effect what the district court advised the jury when it instructed that the claimed method does not contain time limitations and that the claimed method is performed when each of the three steps is completed.

Smith & Nephew interprets the court's claim construction to require that the return electrode never touch the body until all the claimed steps are completed. That interpretation, however, is not faithful to the claim construction that the trial court adopted, and it is not a convincing interpretation of the claim language. When the district court construed the claim language at issue here, it rejected Smith & Nephew's

proposed construction, which was that the return electrode must never touch the body at any time during the surgery. The court properly rejected that proffered claim construction on the ground that it imposed an unclaimed temporal requirement on the method. In effect, Smith & Nephew is now advancing that rejected claim construction, while maintaining that it has accepted the district court's construction. We uphold the district court's claim construction and reject Smith & Nephew's argument that the court's construction was actually a version of the very construction that the court rejected before trial.

Substantial evidence at trial showed that Smith & Nephew's probes were used so that the return electrode did not touch the body at a time when all the other claim limitations were met. ArthroCare's expert stated that during surgery "the return electrode is positioned back . . . so that you try to make sure that it's not in contact" with the body. Even Smith & Nephew's expert admitted that there were instances in which the return electrode was not in contact with the body during certain steps of the claimed method. Additionally, upon viewing the videotaped electrosurgeries, project managers for two of Smith & Nephew's accused probes admitted that the return electrodes were not in contact with body tissue during use.

There was also strong circumstantial evidence that Smith & Nephew's probes were used in an infringing manner, and that Smith & Nephew induced users to employ the probes in that way. Smith & Nephew's witnesses confirmed that the return electrodes of the accused probes were not designed or intended to contact the body tissue when power was being applied to the device. That evidence was supported by testimony from ArthroCare's expert. Moreover, the sales literature accompanying one

of the accused devices instructs surgeons that "care should be taken to prevent tissue contact with the return electrode." That literature explains why the surgeon should avoid touching the return electrode to the body tissue. Even though the return electrode on the accused probe is enlarged so as to lower the return current density and thus reduce the risk of burns, the return electrode of the Smith & Nephew device was still not supposed to touch the body during the application of power because "[w]hile it will not be as hot as the active electrode at the distal tip, the return electrode may become heated. For this reason, it is important to avoid inadvertent contact with the tissue." Instruction manuals for the other accused probes similarly confirm that the return electrode should be completely surrounded by or immersed in saline during use. Thus, substantial evidence supports the jury's determination that Smith & Nephew indirectly infringed the claimed method. We therefore affirm the district court's denial of judgment as a matter of law with respect to the '592 patent.

Each party shall bear its own costs for this appeal.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, and REMANDED.

**04-1323, -1487**

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**UNITED STATES COURT OF APPEALS**
**FOR THE FEDERAL CIRCUIT**

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ARTHROCARE CORPORATION,

*Plaintiff/Counterclaim Defendant-Appellee,*

and

ETHICON, INC.,

*Counterclaim Defendant-Appellee,*

v.

SMITH & NEPHEW, INC.,

*Defendant/Counterclaimant-Appellant,*



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Appeal from the United States District Court for the District of Delaware in Case No. 01-CV-504, Chief Judge Sue L. Robinson

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# COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC* BY PLAINTIFF/COUNTERCLAIM DEFENDANT-APPELLEE ARTHROCARE CORPORATION

Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Timothy E. DeMasi
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

Jack B. Blumenfeld
Karen Jacobs Louden
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 North Market Street
Wilmington, DE 19899
(302) 658-9200

*Attorneys for ArthroCare Corporation*

## CERTIFICATE OF INTEREST

Counsel for Plaintiff/Counterclaim Defendant-Appellee ArthroCare Corporation certifies the following information in compliance with Rule 26.1 of the Federal Rules of Appellate Procedure and Rules 26.1 and 47.4 of the Federal Circuit Rules, and in satisfaction of Rule 12(b) of the Federal Rules of Appellate Procedure requiring a Representation Statement:

1. The full name of every party represented by me is: ArthroCare Corporation.

2. The names of the real parties in interest represented by me are the same as those identified in paragraph 1 above.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party represented by me are: None.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this Court are:

Weil, Gotshal & Manges LLP attorneys:
Matthew D. Powers
Jared Bobrow
Timothy E. DeMasi
Perry Clark
David Pollock

Morris, Nichols, Arsht & Tunnell attorneys:
Jack B. Blumenfeld
Karen Jacobs Louden
James W. Parrett, Jr.

Dated: May 21, 2004

Respectfully submitted,

By: 

Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Attorneys for Plaintiff/Counterclaim
Defendant-Appellee ArthroCare Corporation

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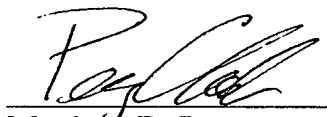
## STATEMENT OF COUNSEL

Based on my professional judgment, I believe that the panel decision is contrary to the following precedents of this Court: *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1348 n.2 (Fed. Cir. 1999) (where "neither party disputes [the District Court's] construction on appeal, we decline to raise an issue *sua sponte* that the parties have not presented").

Dated: May 21, 2005

WEIL, GOTSHAL & MANGES LLP



Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

*Attorneys of record for ArthroCare Corp.*

## POINTS OF LAW AND FACT OVERLOOKED OR MISAPPREHENDED BY THE COURT

1. The Court made a material error in reversing the jury's verdict that the '536 Patent is not anticipated by overlooking that the asserted claims of the '536 Patent require an "electrically conducting fluid supply" *outside* the patient's body "for directing electrically conducting fluid to the target site" *in addition to* requiring that the "electrically conducting fluid generate[] a current flow path" *inside* the patient's body.

2. The Court overlooked and misapprehended the District Court's unchallenged claim construction of "electrically conducting fluid" and improperly substituted and applied its own *sua sponte* claim construction.

3. The Court misapprehended the standard of review governing appeals from the denial of a Rule 50 motion by, among other things, improperly weighing the evidence, deciding disputed facts, and combining two prior art references to find anticipation.

4. The Court misapprehended its role as a reviewing court and improperly vacated the injunction, even though it affirmed the jury's verdict that Smith & Nephew infringed the '882 Patent and the'592 Patent.

## ARGUMENT IN SUPPORT OF REHEARING

### I. The Court Overlooked That The '536 Patent Requires An "Electrically Conducting Fluid Supply" Outside The Patient's Body

The Court framed the issue of anticipation as whether the Roos References disclose an "electrically conducting fluid." Decision at 9. The Court focused its anticipation analysis on whether the fluid in the Roos References creates a current flow path between the active and return electrodes *inside the patient's body*. *Id.* at 9-12. In doing so, the Court overlooked that Claim 45 also requires that the fluid must be an electrically conducting *outside the patient's body*. Claim 45 provides in relevant part:

> an *electrically conducting fluid supply for directing electrically conducting fluid to the target site* such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal. A399.

The District Court's unchallenged construction of the phrase "electrically conducting fluid supply" was "a medical container that stores electrically conducting fluid," which necessarily requires that the fluid be electrically conducting outside the patient's body. A17. ArthroCare specifically argued on appeal that the Roos References do not disclose an "electrically conducting fluid supply for directing electrically conducting fluid to the target site." ArthroCare's Br. at 27. The Court never addressed this limitation and never pointed to any clear and convincing disclosure in the Roos References that the fluid was electrically

conducting *before* it was delivered to the target site inside the patient's body. As a result, the Court's finding of anticipation violates Federal Circuit precedent which requires that an anticipating reference disclose each and every limitation of the asserted claims by clear and convincing evidence. *Koito Mfg. Co. Ltd. v. Turn Key Tech., LLC*, 381 F.3d 1142, 1151 (Fed. Cir. 2004).

None of the passages from the Roos References on which the Court relies provides clear and convincing evidence of an "electrically conducting fluid supply" outside the patient's body. In each case, the evidence before the jury fully supports the conclusion that the Roos References used fluid that was non-conductive outside the patient's body.

The statement in Claim 1 of the Roos Patent that there is a space between the electrodes that is "adapted to be filled with liquid to provide electrical conductance" is satisfied by a non-conductive fluid outside the patient's body that becomes more conductive once it mixes with secretions inside the patient's body. A later issued patent to Roos, the '667 Patent, made clear that the Roos Patent relied (unsuccessfully) on tissue secretions inside the body to make the electrically non-conducting fluid more conducting. A15517 (1365:25-1367:21); A23661 (1:14-29). Likewise, the statement in the Roos prosecution history that "there is always a well-defined current path . . . through the washing (and tissue) fluid" is consistent with the explanation in the Roos '667 Patent that secretions inside the

patient's body (*i.e.* tissue fluid) seeped into the delivered non-conductive fluid to make it more conductive.

The Court also relied on diagrams and text in the Roos Article describing "very good electrical conditions" and providing "the high-frequency a current path . . . offering such low resistance that aberrant currents or leakage currents do not even occur." Again, this is consistent with using secretions, such as blood, inside the body to increase the conductivity of the "irrigation liquid" that was non-conductive outside the body. The Roos Article states that Roos and Elsässer used their bipolar device inside the patient's body only *after* they had used a conventional monopolar device to make "initial cuts" in the patient's tissue in the presence of the "irrigation liquid." A18730. Because the evidence uniformly showed that monopolar TURP procedures were performed using non-conductive fluid, A15510 (1339:15-1340:5); A15512-13 (1348:7-1349:1); A15519 (1374:23-1375:12), this strongly supports the jury's inference that Roos did not disclose an "electrically conducting fluid supply" outside the patient's body for directing electrically conducting fluid to the target site."

Because this Court overlooked the "electrically conducting fluid supply" limitation of Claim 45, and because there was substantial evidence that an "electrically conducting fluid supply" was not disclosed in the Roos References, the jury's verdict of no anticipation should be affirmed.

## II. The Court Overlooked And Misapprehended The Unchallenged Claim Construction Of "Electrically Conducting Fluid"

The District Court construed "electrically conducting fluid" to mean "any fluid that facilitates the passage of electrical current. Examples of electrically conducting fluid are blood and saline." A18. On appeal, Smith & Nephew did not challenge this construction. Nonetheless, this Court did not apply this construction. The Court's decision never discusses or evaluates whether the "irrigation liquid" in the Roos References was capable of "facilitating the passage of electrical current." Instead, the Court *sua sponte* defined an "electrically conductive fluid" as one that merely "provide[s] a path for the current" and evaluated the jury's no anticipation verdict using its substituted claim construction. Decision at 12 ("the Roos and Elsässer article describes the liquid as providing a path for the current, thus serving as a conductive fluid"). This is improper.

By ignoring the District Court's unchallenged claim construction, and substituting its own without briefing on the issue, this Court dangerously departs from its own precedent. *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1348 n.2 (Fed. Cir. 1999) (where "neither party disputes [the District Court's] construction on appeal, we decline to raise an issue *sua sponte* that the parties have not presented"). *WMS Gaming* reflects sound policy. It recognizes that the Court is not in a position to determine the proper meaning of claim terms when the parties have not briefed the issues and directed the Court to the relevant evidence.

None of the briefs, evidence, or argument on which the District Court decided claim construction was brought to the Court's attention. Had those materials been before this Court, it would have been clear why this Court's *sua sponte* construction is incorrect.

The most significant problem with this Court's construction is that it reads-out the words "electrically conducting" from the phrase "the electrically conducting fluid generates a current flow path." By defining "electrically conducting fluid" to mean "fluid that provides a path for the current," this Court rewrites Claim 45 to read: "the ~~electrically conducting fluid~~ [fluid that provides a path for the current] generates a current flow path." This construction improperly conflates the claimed structure ("electrically conducting fluid") with the claimed function ("generat[ing] a current flow path") by defining the structure solely in terms of the function it performs. This violates this Court's prohibition on rendering claim terms meaningless under the guise of claim construction. *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005) (reversing District Court construction that "reads-out the essence" of a claim limitation).[1]

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1 The Court's *sua sponte* construction also is erroneous because it effectively adopts the construction that Smith & Nephew proposed below – "fluid that allows the passage of electrical current" – that the District Court rejected and from which Smith & Nephew did not appeal. A7549.

This Court's new claim construction represents a material error because, had this Court given effect to the District Court's construction, there is substantial evidence that the Roos References do not disclose by clear and convincing evidence an electrically conducting fluid that "that facilitates the passage of electrical current." The Roos Patent mentions a fluid for "providing electrical conductance" and the Roos Patent prosecution history mentions a "current path" but, as Smith & Nephew's own expert admitted at trial, the non-conducting fluids conventionally used in TURP procedures (the procedure described in the Roos References), such as glycine and mannitol, can provide electrical conductance. A15519 (1374:23-1375:9); A15520 (1377:9-1378:1); A15510 (1340:6-10). Providing electrical conductance, which even non-conducting fluids do in electrosurgery, is not the same as "facilitating" current flow. Similarly, the Roos Article mentions providing "the high frequency current a path" and a current "directly flowing" through the fluid, but neither of these statements teaches that the current flow is greater than the flow of current through the numerous non-conductive fluids commonly used in electrosurgery.[2]

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[2] Both the Roos Patent and the Roos Article teach that non-conductive fluids used in electrosurgery provide current flow paths. A18720 (Figs. 2 & 3); A18676 (1:28, 1:52-56); A15517 (1366:17-20); A15519 (1374:23-1375:9); A15520 (1377:9-1378:1); A15510 (1340:6-10). Additional evidence before the District Court also established that a person of ordinary skill would have recognized that non-electrically conducting fluids can provide current pathways, even though they are not considered "electrically conducting fluids." *See* Addendum at A5956 (Pearce

Because the Court should not have applied its own *sua sponte* claim construction, and because there is substantial evidence supporting the verdict of no anticipation under the District Court's unappealed claim construction, the jury's verdict of no anticipation of the '536 Patent should be affirmed.

## III. The Court Misapprehended Its Proper Role In Reviewing Smith & Nephew's Rule 50 Motion

### A. The Court Improperly Weighed The Evidence And Decided Disputed Facts Contrary To The Jury's Verdict

This Court improperly weighed evidence and decided at least three disputed facts contrary to the jury's verdict in this case, thus overlooking the well-settled rule that, in reviewing a JMOL decision, this Court "do[es] not weigh the evidence, consider the credibility of witnesses, or decide disputed facts." *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1289-90 (Fed. Cir. 2000) ("We determine whether, 'viewing the evidence in the light most favorable to the non-moving party,' and giving the non-movant 'the benefit of all reasonable inferences,' there is sufficient evidence of record to support a jury verdict in favor of the non-movant.").

First, the Court improperly decided that some bipolar embodiments in the Roos References use electrically conducting fluid – a disputed fact. The Court concedes that the embodiments in Figures 1 and 5 of the Roos Patent do not use

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at 25) (fluid used in TURP procedures "carries heat away and disperses current (even though it is non-conductive)").

electrically conducting fluid, but states that this is irrelevant because they are only "one" or "a single" embodiment. Decision at 11. There is no basis for this inference, however, because the evidence at trial showed that the Roos References describe the fluid used with *all* embodiments in the same way, never stating or suggesting that different fluids are used with different embodiments. A15513 (1350:20-1351:6); A15519 (1376:11-25). Moreover, the one bipolar embodiment that this Court identifies as using electrically conducting fluid (Figure 1 in the Roos Patent) is precisely the same embodiment that Smith & Nephew's expert admitted did *not* use electrically conducting fluid. *Compare* Decision at 11 (citing "'198 Patent col. 3, ll. 9-15" (the "plastic extension" refers to element 18 in Figure 1 of the Roos Patent)) *with* A15516-17 (1363:2-1367:21) (Smith & Nephew's expert admitting that the embodiment of Figure 1 must have been used with non-conducting liquid). The Court's inference is thus in conflict not only with the reasonable inference drawn by the jury but also by the evidence on which it relies.

Second, this Court improperly weighed the evidence and decided that it "is unclear" whether the fluid used in Roos's monopolar embodiments was non-conductive—a disputed fact. Based on its resolution of conflicting evidence, the Court inferred that the Roos References disclose conductive fluid inside a patient's

body.[3] Decision at 10-11. The Court's conclusion, however, is directly contrary to the undisputed evidence at trial (from Smith & Nephew's own expert) that the fluid used in all of Roos's monopolar embodiments was non-conductive. A15511 (1342:15-24); A15519 (1374:8-1376:25). The Court further overlooked the undisputed evidence (also from Smith & Nephew's expert) that the Roos References describe the fluid identically for all embodiments, both bipolar and monopolar. A15511 (1343:16-1344:6); A15519 (1375:22-1376:25). Because the Roos References show current flow through the fluid used with both the monopolar and the bipolar embodiments, and because the monopolar fluid was non-conductive and described in the same terms as the fluid used with the bipolar devices, the jury reasonably inferred that non-conductive fluid was used in all Roos embodiments. The Court improperly substituted its own inference for a reasonable jury inference.

Third, the Court improperly weighed the evidence and decided that "it would be bizarre to say that a non-conductor was introduced to 'provide electrical conductance'" – a disputed fact. Decision at 10 (citing Claim 1 of the Roos

[3] On this point, the Court clearly weighed conflicting evidence and drew an inference contrary to an inference drawn by the jury (and which the District Court found entirely reasonable): "The [District] Court reasoned that because most monopolar devices use nonconducting fluid, the Roos patent does not clearly teach electrically conducting fluid. That inference, however, is contradicted by the claim language and prosecution history of the Roos patent reviewed above." Decision at 11.

Patent). The jury's decision to draw the contrary inference is not "bizarre" because there was myriad evidence before it that fluids used in TURP procedures, such as glycine and mannitol, were considered electrically non-conducting by those of skill in the art even though they provide some electrical conductance. A15517 (1366:17-20); A15519 (1374:24-1375: 9); A15520 (1377:9-1378:1). Moreover, the "provide electrical conductance" language appears in Claim 1 of the Roos Patent. The bipolar device shown in Figure 1 of the Roos Patent embodies Claim 1, A15513 (1349:23-1350:11), and it was undisputed at trial that the later-issued Roos '667 Patent stated that the neutral electrode of the Roos Patent's Figure 1 embodiment "can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process." A15516 (1363:2-22); A23661 (1:14-29). Based on this description, Smith & Nephew's expert agreed that Roos's "washing liquid" could not have been electrically conducting because, if it were, then "the secretion which is present during the cutting process" would not have been needed for the active and return electrodes to make electrical contact. A15517 (1365:25-1366:7). This demonstrates that a non-conductive fluid can "provide electrical conductance," just as the jury must have found.

### B. The Court Improperly Relied On A Combination of Multiple References In Finding That The Roos Patent Anticipates

By combining the Roos Patent and the Roos Patent prosecution history to

conclude that the Roos Patent anticipates the asserted claims of the '536 Patent, the Court overlooked the rule that anticipation must be found in a single reference. "It is hornbook law that anticipation must be found in a single reference, device, or process," unless the additional reference is used to shed light on what a particular reference "would have meant to those of skill in the art." *Studiengesellschaft Kohle, M.B.H. v. Dart Indus.*, 726 F.2d 724, 726-27 (Fed. Cir. 1984).

Here, the Court explicitly stated that it was relying on the Roos prosecution history in concluding that the Roos Patent discloses electrically conducting fluid: "[t]he prosecution history of the Roos patent makes clear that the 'fluid provid[ing] electrical conductance' recited in claim 1 of the Roos patent reads on the 'electrically conducting fluid' of the '536 patent." Decision at 10. The Roos Patent and its prosecution history, however, are not a single reference. Moreover, no witness testified at trial that a person of ordinary skill would have understood that the passage from the prosecution history means that the "providing electrical conductance" language describes an electrically conducting fluid. As such, this Court's reliance on multiple references was a material mistake of law, without which this Court would not have concluded that the Roos Patent anticipates.

## IV. The Court Misapprehended That Smith & Nephew's Infringement Of The '882 and '592 Patents Warrants Maintaining The Injunction

The Court should reinstate the injunction and allow the District Court to determine whether the injunction should be set aside on remand. The infringement

determinations that were not reversed by the Court—Smith & Nephew's infringement of the '882 and '592 Patents—entitle ArthroCare to a permanent injunction, *see, e.g., MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005), and that relief and protection should not be taken away absent a firm legal basis.

Rather than relying on any of the customary grounds for dissolving an injunction—legal error, overbreadth, or a failure to comply with specificity and fact-finding requirements, *see, e.g., Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 986 F.2d 476, 479-80 (Fed. Cir. 1993); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993); FED. R. CIV. P. 65—the Court lifted the injunction as a matter of deference. Decision at 7-8. This is improper. Reconsideration of the injunction should be left to the District Court, which has broad discretion under 35 U.S.C. § 283 to determine the scope of injunctive relief. *See, e.g., Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 945 (Fed. Cir. 1992). Once the District Court has exercised its discretion, this Court can review that decision, should it be appealed.

## ARGUMENT IN SUPPORT OF REHEARING *EN BANC*

Rehearing *en banc* is necessary in this case to maintain uniformity of this Court's decisions. FED. R. APP. P. 35(a)(1). The panel, without briefing or argument, *sua sponte* rejected the District Court's unappealed construction of

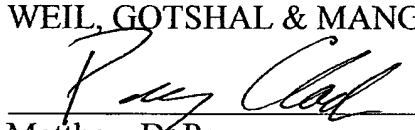
"electrically conducting fluid" and substituted its own, inconsistent construction of the phrase. Indeed, the Court, in effect, adopted the claim construction that Smith & Nephew proposed below, that the District Court rejected after a *Markman* hearing, and that Smith & Nephew did not appeal. This is contrary to the holding of *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1348 n.2 (Fed. Cir. 1999), that when "neither party disputes [the District Court's] construction on appeal, we decline to raise an issue *sua sponte* that the parties have not presented." The panel's *sua sponte* claim construction, if allowed to stand, would set a dangerous precedent. Such *sua sponte* constructions promote error, because the Court is not presented with briefing, argument, or evidence from which to make the correct decision. They also violate well-settled doctrines of prudence and of limiting the exercise of judicial power to ripe, active disputes.

## CONCLUSION

For these reasons, the jury's verdict that the '536 Patent is not anticipated should be affirmed and the District Court's injunction should be reinstated.

Dated: May 21, 2005

WEIL, GOTSHAL & MANGES LLP



Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065; Tel: (650) 802-3000
*Attorneys of record for ArthroCare Corp.*

## ADDENDUM

# United States Court of Appeals for the Federal Circuit

04-1323, -1487

ARTHROCARE CORPORATION

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

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DECIDED: May 10, 2005

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Before MAYER, LOURIE, and BRYSON, Circuit Judges.

BRYSON, Circuit Judge.

The term electrosurgery refers to a surgical technique in which high frequency electrical current is applied to cut or ablate body tissue. There are two forms of electrosurgical devices, monopolar and bipolar. In monopolar devices, electric current passes from a single exposed electrode into the body tissue that is to be ablated. The current then passes through the body to a return electrode, usually attached to the outside of the patient's body. In bipolar devices, both electrodes are inserted into the

body. The current passes from one electrode, through the targeted body tissue, and then back to the return electrode.

Electrosurgery has the benefit of reducing patient bleeding and trauma. However, there are disadvantages to applying high voltages within the patient's body, including the risk that the electrical discharge will cause damage other than to the target tissue. For that reason, the path of the electrical current through the body needs to be carefully controlled. Moreover, surgeons prefer to cleanse the surgical area during arthroscopic procedures with fluids that conduct electricity, such as saline. Therefore, electrosurgical devices need to be usable in such fluids. The patents at issue in this case sought to address the problems of controlling the electrical path and enabling electrosurgical instruments to function in the presence of conductive fluids.

The three patents at issue, U.S. Patent Nos. 5,697,536 ("the '536 patent"), 5,697,882 ("the '882 patent"), and 6,224,592 ("the '592 patent"), are owned by ArthroCare Corporation. ArthroCare sued Smith & Nephew, Inc., in the United States District Court for the District of Delaware claiming that Smith & Nephew was liable for infringement of those patents based on its manufacture of certain electrosurgical probes and the use of those probes in surgery. In response, Smith & Nephew filed a counterclaim alleging that ArthroCare and Ethicon, Inc., had violated the antitrust laws by entering into a conspiracy in restraint of trade. Smith & Nephew's theory of antitrust liability was that ArthroCare and Ethicon had settled an earlier dispute in a manner designed to restrain other competitors from entering the market for electrosurgical devices and that ArthoCare had brought this action, although knowing it to be

objectively baseless, as part of an unlawful conspiracy with Ethicon to interfere with Smith & Nephew's business.

Before trial, the district court bifurcated the case. The first phase encompassed the patent issues of infringement, invalidity, and inequitable conduct. The second phase addressed damages, willfulness, and the antitrust counterclaim. The court stayed the second phase until after completion of the trial on the first.

At the conclusion of the patent trial, the jury determined that Smith & Nephew had directly or indirectly infringed the three patents and that none of the patents were invalid. Smith & Nephew then moved for judgment as a matter of law and a new trial. ArthroCare meanwhile moved to dismiss Smith & Nephew's antitrust counterclaim for failure to state a claim upon which relief could be granted. Before Smith & Nephew's response to that motion was due, the district judge stayed all proceedings on the antitrust counterclaim while she considered Smith & Nephew's motions for judgment as a matter of law and a new trial. The court eventually denied Smith & Nephew's motions and entered a permanent injunction against Smith & Nephew. ArthroCare Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 681 (D. Del. 2004). On the same day, the court granted ArthroCare's motion to dismiss the antitrust counterclaim before Smith & Nephew responded to the motion. Smith & Nephew sought reconsideration of the dismissal order, but the court denied the motion for reconsideration. ArthroCare Corp. v. Smith & Nephew, Inc., 315 F. Supp. 2d 615, 618 (D. Del. 2004). In denying reconsideration, the court stated that the order staying proceedings on the antitrust counterclaim had stayed only discovery and trial of the counterclaim and did not affect the motion to dismiss. The court further stated that Smith & Nephew's reliance on a

statement by the court in a June 2003 telephone conference was misplaced, and that if Smith & Nephew "believed that ArthroCare's motion [to dismiss] was premature and inconsistent with" the court's stay order, it should have indicated so, presumably in a more formal manner. Id. at 318 n.3. The court added that it was "not persuaded that any argument from Smith & Nephew about the basis for its antitrust allegations will change the court's decision." Id. at 319.

I

On appeal, Smith & Nephew first argues that the district court erred in dismissing the antitrust counterclaim without giving it an opportunity to respond to the motion to dismiss or to amend its counterclaim. Following the trial on the patent issues, the district court continued the stay of the antitrust proceedings pending the disposition of Smith & Nephew's motions for judgment as a matter of law and a new trial, and ArthroCare's request for an injunction. After the court ruled on those matters, however, the court dismissed the antitrust counterclaim even though it had not received a response to the motion to dismiss from Smith & Nephew. The court noted that Smith & Nephew had not filed a response to the motion and from its silence "presume[d] that Smith & Nephew does not oppose the motion." Moreover, the court concluded that the "sham litigation" aspect of Smith & Nephew's antitrust counterclaim was baseless. The court did not address the other ground for the antitrust counterclaim, namely, the allegation that ArthroCare and Ethicon had entered into a settlement of their dispute that was designed to exclude other competitors, including Smith & Nephew, from the relevant market.

Smith & Nephew contends that, because of the stay of proceedings on the antitrust counterclaim, it never had an opportunity to respond to the motion to dismiss. In the absence of an opportunity to respond, Smith & Nephew contends that it was error for the court to grant the motion to dismiss.

In its opinion on reconsideration, the district court characterized the pretrial order staying proceedings on the antitrust counterclaim as staying discovery and trial but not the motion to dismiss. While it is true that the written stay order referred only to discovery and trial, the court elaborated on that order in a June 9, 2003, telephone conference, in which the court stated that proceedings on the pending motion to dismiss the antitrust counterclaim were stayed. In response to a question about the pending motion to dismiss, the court stated that "everything is stayed and we'll deal with the antitrust issues later. . . . So the pending motion [to dismiss] on antitrust is stayed and everything having to do with the antitrust counterclaims, discovery, substantive motions, et cetera, is stayed pending further order of the court." In light of that colloquy, it was reasonable for Smith & Nephew to conclude that the stay order extended to the proceedings on the motion to dismiss and that it would not be required to respond to the dismissal motion until the stay was lifted. Thus, the effect of this sequence of events was that the court granted ArthroCare's motion to dismiss the antitrust counterclaim without giving Smith & Nephew an opportunity to respond to the motion.

The Supreme Court has stated that under Rule 12(b)(6) of the Federal Rules of Civil Procedure, "a plaintiff with an arguable claim is ordinarily accorded notice of a pending motion to dismiss for failure to state a claim and an opportunity to amend the complaint before the motion is ruled upon." Neitzke v. Williams, 490 U.S. 319, 329

(1989). The purpose of such a procedure is to enable the plaintiff "meaningfully to respond by opposing the motion to dismiss on legal grounds or by clarifying his factual allegations so as to conform with the requirements of a valid legal cause of action." Id. at 329-30. Providing the plaintiff with an opportunity to respond "crystallizes the pertinent issues and facilitates appellate review of a trial court dismissal by creating a more complete record of the case." Id. at 330.

The Third Circuit, whose law applies to this procedural issue, has extended that principle by adopting a categorical rule that "a Rule 12(b)(6) motion for dismissal . . . may be disposed of only after a hearing, which affords an opportunity to present legal arguments either orally, in writing, or both at the District Court's discretion." Dougherty v. Harper's Magazine Co., 537 F.2d 758, 761 (3d Cir. 1976); see also Oatess v. Sobolevitch, 914 F.2d 428, 430 n.5 (3d Cir. 1990) (a district court may not dismiss a complaint under Rule 12(b)(6) sua sponte without giving the plaintiff a chance to respond). In this case, Smith & Nephew did not have an opportunity to respond to the motion to dismiss, in contravention of that rule.

ArthroCare and Ethicon claim that Smith & Nephew was given the opportunity to contest the motion to dismiss in the form of its motion for reconsideration, which the district court denied. That argument is flawed for several reasons. In Dougherty, the plaintiff also petitioned the district court for reconsideration, yet the Third Circuit reversed the district court for dismissing the case without giving the plaintiff an opportunity to respond. 537 F.2d at 761; see also Jordan v. County of Montgomery, Pa., 404 F.2d 747, 748 (3d Cir. 1969) (finding that "the district court erred in dismissing [the plaintiff's] complaint on the defendants' motions without affording him an

opportunity to submit a written statement in opposition to the motions" even though the plaintiff made a motion for relief from judgment under Rule 60(b)(1)). Additionally, when it denied Smith & Nephew's motion for reconsideration, the district court did not conduct a de novo analysis of the motion to dismiss, but instead applied the highly restrictive standard applicable to reconsideration motions. See ArthroCare, 315 F. Supp. 2d at 618. The reconsideration process thus did not satisfy the requirement that Smith & Nephew be given the opportunity "meaningfully to respond" to the motion to dismiss.

On the merits, ArthroCare and Ethicon argue that Smith & Nephew's counterclaim should fail because the claim does not describe the antitrust injury sufficiently and does not provide enough specificity in describing the antitrust violation. Third Circuit precedent indicates, however, that if a claim fails for lack of specificity, the district court should grant leave to amend the complaint, regardless of whether the complainant asks for it. Shane v. Fauver, 213 F.3d 113, 116 (3d Cir. 2000); Borelli v. City of Reading, 532 F.2d 950, 951 n.1 (3d Cir. 1976). The court should dismiss only if the complainant is unable or unwilling to amend the complaint. Dist. Counsel 47 v. Bradley, 795 F.2d 310, 316 (3d Cir. 1986). We therefore vacate the district court's dismissal of the antitrust counterclaim and direct the court to allow Smith & Nephew to respond to the motion to dismiss. If the court concludes, as urged by ArthroCare and Ethicon, that Smith & Nephew's antitrust counterclaim fails for lack of specificity, Smith & Nephew should be given the opportunity to amend.

Because we dispose of the counterclaim issue on a procedural ground, we take no position on the merits of the counterclaim. However, we note that the district court did not intend to issue a permanent injunction until after it disposed of the antitrust

counterclaim. Because the district court must reconsider that counterclaim on remand, the permanent injunction against Smith & Nephew must be vacated pending the disposition of the antitrust counterclaim. See Tegal Corp. v. Tokyo Electron Am., Inc., 257 F.3d 1331, 1351 (Fed. Cir. 2001).

II

Smith & Nephew next appeals the denial of its motion for judgment as a matter of law that the asserted claims of the '536 patent (claims 46, 47, and 56) were anticipated by a prior art patent, U.S. Patent No. 4,116,198 ("the Roos patent" or "the '198 patent"), and an article by the inventor of that patent, Eberhard Roos and a co-author, E. Elsässer.

As an initial matter, ArthroCare argues that Smith & Nephew is precluded from arguing invalidity on appeal. ArthroCare maintains that Smith & Nephew did not specify the basis on which it sought judgment as a matter of law after presenting its evidence at trial, as required by Rule 50 of the Federal Rules of Civil Procedure. Because of that failure, ArthroCare claims that Smith & Nephew may not assert invalidity now. That argument has no merit, however, because the district judge acknowledged that she precluded argument on the motions for judgment as a matter of law at trial and indicated that Smith & Nephew's rights were preserved.

On the merits, the '536 patent is directed to an electrosurgical system. The three asserted claims of the '536 patent all recite an electrosurgical probe "comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply." The claims also recite "an

electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal." ArthroCare maintains that neither the Roos patent nor the Roos and Elsässer article teaches either an electrically conducting fluid or an electrosurgical probe with a connector at the proximal end connecting the probe to the power supply. We disagree and hold that the evidence at trial clearly established that the prior art references disclose both of those features.

A

With respect to the "electrically conductive fluid" limitation, claim 1 of the Roos patent recites that the claimed electrode is "adapted to be filled with liquid to provide electrical conductance." '198 patent, col. 7, ll. 60-62. ArthroCare posits that there is a legally tenable distinction between a fluid that provides electrical conductance and "an electrically conducting fluid." In particular, ArthroCare argues that while all materials provide some electrical conductance, most do not possess a sufficiently high level of conductivity for a person of skill in the art to consider them "electrically conductive."

ArthroCare's distinction is belied by the description of "electrically conducting fluid" in the '536 patent and by the prosecution history of the Roos patent, which together make clear that both patents recite a fluid that provides a path for the electrical current between the electrodes of the electrosurgical devices. The '536 patent explains that the conducting fluid provides a "current flow path between the target site and the return electrode." '536 patent, col. 3, ll. 27-30; id., col. 7, ll. 35-46. The inventor of the '536 patent affirmed that he used the term "conducting fluid" in the '536 patent to indicate that the fluid "provides the pathway between the active electrode or electrodes,

plural, and the return electrode." Furthermore, the description of the fluid in the patent indicates that the conducting fluid facilitates the passage of current by providing a low electrical impedance current path between the two electrodes. Id., col. 7, ll. 40-43.

The prosecution history of the Roos patent makes clear that the fluid "provid[ing] electrical conductance" recited in claim 1 of the Roos patent reads on the "electrically conducting fluid" of the '536 patent. The Roos patent prosecution history notes that the washing fluid recited in claim 1 of the Roos patent must "provide the necessary electrical conductor" between the electrodes and that "there is always a well-defined current path . . . through the washing (and tissue) fluid." Thus, the Roos patent describes a fluid that creates a "current flow path." That description of the fluid makes sense given the language of claim 1 of the Roos patent, which recites that the liquid "provides electrical conductance between said electrodes." That language means that the fluid is introduced during electrosurgery to provide conductance and to help generate a "current flow path." While it is true that, given enough voltage, an electrical current can be made to flow through any substance, it would be bizarre to say that a non-conductor was introduced to "provide electrical conductance." Consequently, we conclude that the Roos patent discloses an electrically conducting fluid.

The district court provided three reasons for concluding that the Roos patent does not teach an electrically conducting fluid. First, the court reasoned that the Roos patent does not disclose such a fluid because it does not list either saline or Ringer's lactate as an example of an electrically conducting fluid. That rationale is unconvincing, however, because there is no requirement that an anticipating reference must provide specific examples; rather, the reference need only "be enabling and describe the

applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention." In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994). Second, the district court focused on the fact that the Roos patent specification does not distinguish between the fluid used in monopolar devices and the fluid used in bipolar devices. The court reasoned that because most monopolar devices use nonconducting fluid, the Roos patent does not clearly teach conducting fluid. That inference, however, is contradicted by the claim language and prosecution history of the Roos patent reviewed above. Finally, the court looked to an embodiment described in the Roos patent in which the probe touches the tissue. The court concluded that there would be no need for electrical contact with the patient's tissue if the fluid were conducting. The court's analysis, however, focused on only one embodiment in the Roos patent. There are other embodiments in the patent as to which it is clear that no such direct contact is necessary, see, e.g., '198 patent, col. 3, ll. 9-15, and it was error for the district court to limit the disclosure of the prior art reference to a preferred embodiment. See Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc., 127 F.3d 1065, 1068 (Fed. Cir. 1997). ArthroCare makes a similar point, contending that another embodiment described in the Roos patent uses non-conducting fluid. In support of its argument, ArthroCare points to a later patent by Roos, which describes the foreign patent to which the Roos patent claimed priority. Like the district court's analysis, however, ArthroCare's argument fails because it addresses only a single embodiment in the Roos patent.

The Roos and Elsässer article also teaches an electrically conducting fluid. The article describes how problems with prior art monopolar devices can be eliminated by

providing "the high-frequency current a path . . . offering such low resistance that aberrant currents or leakage currents do not even occur." The article describes a way of accomplishing that goal by placing a neutral electrode close to the active electrode in an irrigation liquid so that current flows through the liquid. The article states that creating such a current path with the irrigation liquid creates "very good electrical conditions." Furthermore, the diagrams in the Roos and Elsässer article depict current "directly flowing" along a path through the fluid. The description of the role of the irrigation liquid is quite similar to the description of the role of the conducting fluid in the '536 patent, which is to provide a "current flow path between the target site and the return electrode." '536 patent, col. 3, ll. 27-30.

ArthroCare maintains that the article does not teach an electrically conducting fluid because the article uses the term "irrigation liquid" in describing the liquid used in both the bipolar and the monopolar procedures. As we have noted, most monopolar procedures use nonconducting fluids. Because the article does not use different names for the liquids used in the two procedures, ArthroCare contends that there is no way of knowing if the irrigation liquid is a conducting fluid. ArthroCare's argument fails, however, because the article pays little attention to the nature of the irrigation liquid used in the monopolar prior art. It is unclear whether the liquid in the monopolar procedure is nonconductive or whether it is even the same liquid that is used in the bipolar case. What is clear is that, in describing bipolar devices, the Roos and Elsässer article describes the liquid as providing a path for the current, thus serving as a conducting fluid. Even giving ArthroCare the benefit of all reasonable inferences, the

fact that the article uses the same term to refer to the fluid in both procedures does not justify an inference that the fluid described in the bipolar procedure is nonconductive.

B

ArthroCare also maintains that the Roos patent and the Roos and Elsässer article do not disclose "a connector near the proximal end of the shaft for electrically coupling the electrode terminal to the electrosurgical power supply." Both the patent and the article clearly show that the electrodes are coupled to a power source. See, e.g., '198 patent, col. 5, ll. 30-35. Hence, in arguing that the prior art does not anticipate, ArthroCare focuses on the term "connector near the proximal end." However, both the Roos patent and the article disclose such a connector.

The Roos patent states that the claimed invention relates to an electrosurgical device with electrodes and "an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator." '198 patent, col. 1, ll. 5-15; see also id., col. 7, ll. 50-51. The district court construed the term "connector" to mean "a structure that electrically links the electrode terminal to the high frequency power supply." The insulated cable in the Roos patent does exactly that. Specifically, Figure 4 of the Roos patent provides a schematic diagram for the electrosurgical probes in the patent, and it illustrates that the electrodes are connected via "output lines" to a high frequency generator. See id., col. 5, ll. 8-9; id., col. 5, ll. 35-36.

On appeal, ArthroCare appears to accept the district court's construction of the term "connector," but it asserts that the jury could have rejected the contention that a wire is a connector for the purposes of the '536 patent. ArthroCare raises various

arguments concerning whether a wire is a connector, but those arguments miss the point. The district court stated that a connector is a "structure" that electrically links the electrodes and the power supply. That construction of the term "connector" easily encompasses a wire between the electrodes and the power supply. Because ArthroCare does not dispute the district court's construction, ArthroCare's attempt to distinguish "wires" from "connectors" fails. The Roos patent clearly depicts a connector under the district court's construction.

Furthermore, the Roos patent indicates that the electrical wires that connect the electrodes to the power source pass through the probe. The specification of the Roos patent describes one embodiment as having the two electrical leads to the electrodes "pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of the endoscope 13." '198 patent, col. 7, ll. 3-5. In other words, the electrical leads attach to the power source from near the proximal end of the endoscope. While Smith & Nephew's expert agreed that the Roos patent does not explicitly identify the point at which the wires exit the probe, he stated that a person of skill in the art would understand that the wires would be attached to the power source after exiting the back end of the probe. See Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1347 (Fed. Cir. 2000) (even if a piece of prior art does not expressly disclose a limitation, it anticipates if a person of ordinary skill in the art would understand the prior art to disclose the limitation and could combine the prior art description with his own knowledge to make the claimed invention).

A "connector near the proximal end" of the electrosurgical probe is also found in the Roos and Elsässer article. In Figure 8 of the article, the electrosurgical probe is

drawn in cross-section. The figure shows the active and neutral probes attached to wires, and the labels state that those wires go to the power supply. Therefore, a connector is disclosed in the Roos and Elsässer article as well. Moreover, Figure 10 of the article illustrates how those wires leave the probe. That figure is a schematic diagram, which depicts the cutting and neutral electrodes inside the body and projecting from the "resectoscope shaft" on one end. The wires also project from the other end of the shaft, where they connect to a high frequency power source. Thus, the connectors are shown exiting near the proximal end of the probe. The article even provides a photograph of the instrument depicted in Figure 10. The photograph verifies that the electrical leads leave the probe at its back end. In contending that the article does not disclose a connector near the proximal end of the probe, ArthroCare limits its argument to contesting the veracity of Smith & Nephew's expert and disputing his conclusions regarding the presence of the electrical connector in the article. However, the article speaks for itself, and it clearly discloses such a connector.

In sum, Smith & Nephew has proved by clear and convincing evidence that the asserted claims of the '536 patent were anticipated either by the Roos patent or the Roos and Elsässer article. Because the jury's determination that the '536 patent was not invalid is not supported by substantial evidence, we reverse the district court's denial of Smith & Nephew's motion for judgment as a matter of law on that issue.

III

Smith & Nephew also appeals the denial of its motion for judgment as a matter of law that the '882 patent is invalid because the claims of that patent were impermissibly broadened by a certificate of correction. In particular, Smith & Nephew argues that

claim 1 of the '882 patent required three electrodes when it was originally issued, but that after the correction the claim required only two electrodes. Smith & Nephew contends that the change impermissibly broadened the patent's scope.

When ArthroCare originally filed the application that matured into the '882 patent, the claims recited only an "active electrode" and a "return electrode." Before any examination on the merits, ArthroCare changed the claims by making what it termed "a few minor amendments." Those amendments changed the term "active electrode" to "electrode terminal" in three places in claim 1 of the application, but did not make the change in a fourth place, where the term "active electrode" was left unchanged. The prosecuting attorney noted the error on the same day that the patent issued and immediately asked the Patent and Trademark Office to change the remaining reference from "active electrode" to "electrode terminal." The prosecuting attorney testified at trial that the change listed in the certificate of correction was made solely due to a typographical error. Smith & Nephew did not attempt to rebut that evidence.

The correction of a ministerial error in the claims, which also serves to broaden the claims, is allowable if it is "clearly evident from the specifications, drawings, and prosecution history how the error should appropriately be corrected" to one of skill in the art. Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1373 (Fed. Cir. 2001). At trial, Smith & Nephew sought to show that the requisite standard was not met in the case of the correction to the '882 patent. Smith & Nephew's proof on that issue failed to satisfy the jury, and we hold that substantial evidence supports the verdict.

In the first place, claim 1 of the '882 patent does not make sense if it is interpreted to contain three types of electrodes instead of two. The claim requires that

an electrode terminal and a return electrode be coupled to a high voltage source. The claim as originally issued then required that an "active electrode" be placed in close proximity to the target site. High frequency voltage is then applied between the electrode terminal and the return electrode, which induces the discharge of energy to the target site. Nothing in the patent suggests any reason to place a third type of electrode close to the target site. The whole point of the patent is to use the electrode terminal and return electrode to apply a voltage across the tissue; a third type of electrode would serve no apparent purpose. Moreover, the specification refers to "electrode terminal" and "active electrode" interchangeably. See '882 patent, col. 20, ll. 19-21; id., col. 20, ll. 53-54. That evidence indicates that it was clear how the typographical error in the original claims should have been corrected.

The prosecution history further supports ArthroCare's argument that it was unambiguous how the remaining reference to an active electrode in claim 1 should be changed. From the beginning, the claims referred to only two electrodes. The change of the term "active electrode" to "electrode terminal" was made before any examination on the merits, and the uncontroverted evidence establishes that it was meant to be a global renaming. In fact, most of the references to "active electrode" in the claims were changed. Finally, ArthroCare presented unrefuted testimony from an expert who stated that he understood the term "active electrode" in the uncorrected claim to refer to the "electrode terminal."

Smith & Nephew's only evidence that it remained unclear how to fix the error in claim 1 is that claim 53, which depends on claim 1, also refers to "the active electrode." According to Smith & Nephew, that evidence implies that it cannot be apparent how to

fix the remaining instance of "active electrode" in claim 1, because changing it to "electrode terminal" would leave claim 53 without an antecedent basis. In fact, however, a simple explanation for the use of the term "active electrode" in claim 53 is that the prosecuting attorney made another error in claim 53 of the same type that was corrected in claim 1. The prosecuting attorney's failure to replace the term "active electrode" twice in the claims, instead of once, does not demonstrate by clear and convincing evidence that a person of ordinary skill in the art would not understand how to correct those errors. Accordingly, substantial evidence supports the jury's conclusion that the certificate of correction was valid. We therefore affirm the district court's denial of judgment as a matter of law of invalidity of the '882 patent.

IV

Finally, Smith & Nephew appeals the denial of its motion for judgment as a matter of law that it was not liable for indirect infringement of the '592 patent. The '592 patent pertains to a method for conducting electrosurgery. The method comprises positioning an electrode terminal near the target site in the presence of an electrically conductive fluid. Next, a return electrode is positioned in the fluid, while ensuring "that the return electrode is not in contact with the body structure." '592 patent, col. 24, ll. 13-14. Finally, high frequency voltage is applied between the electrode terminal and the return terminal so as to force current to flow into the target site. Smith & Nephew argues that it is not liable for contributory infringement or inducement of infringement of the '592 patent, because there was no evidence that its probes were ever used in a manner that directly infringed the patented method. Smith & Nephew maintains that none of the videotaped surgical procedures using its probes infringed the patented

method because in every case the return electrode was shown touching "the body structure." Smith & Nephew asserts that the jury erred in finding infringement because ArthroCare convinced the jury to disregard the district court's claim construction.

In construing the claims of the '592 patent, the district court instructed the jury that the return electrode "is not to contact the body at all during the performance of the claimed method." The court noted, however, that "[t]he claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed." Smith & Nephew does not challenge that claim construction.

Based upon the district court's claim construction, the jury was free to find infringement if it concluded that the return electrode did not touch the body when each step of the patented method was being performed. There was no need for the electrode to be kept apart from the body throughout the entire surgical procedure; nothing in the claim language or in the court's claim construction required that the electrode not touch the body at any time between the performance of the steps of the claimed process. That is in effect what the district court advised the jury when it instructed that the claimed method does not contain time limitations and that the claimed method is performed when each of the three steps is completed.

Smith & Nephew interprets the court's claim construction to require that the return electrode never touch the body until all the claimed steps are completed. That interpretation, however, is not faithful to the claim construction that the trial court adopted, and it is not a convincing interpretation of the claim language. When the district court construed the claim language at issue here, it rejected Smith & Nephew's

proposed construction, which was that the return electrode must never touch the body at any time during the surgery. The court properly rejected that proffered claim construction on the ground that it imposed an unclaimed temporal requirement on the method. In effect, Smith & Nephew is now advancing that rejected claim construction, while maintaining that it has accepted the district court's construction. We uphold the district court's claim construction and reject Smith & Nephew's argument that the court's construction was actually a version of the very construction that the court rejected before trial.

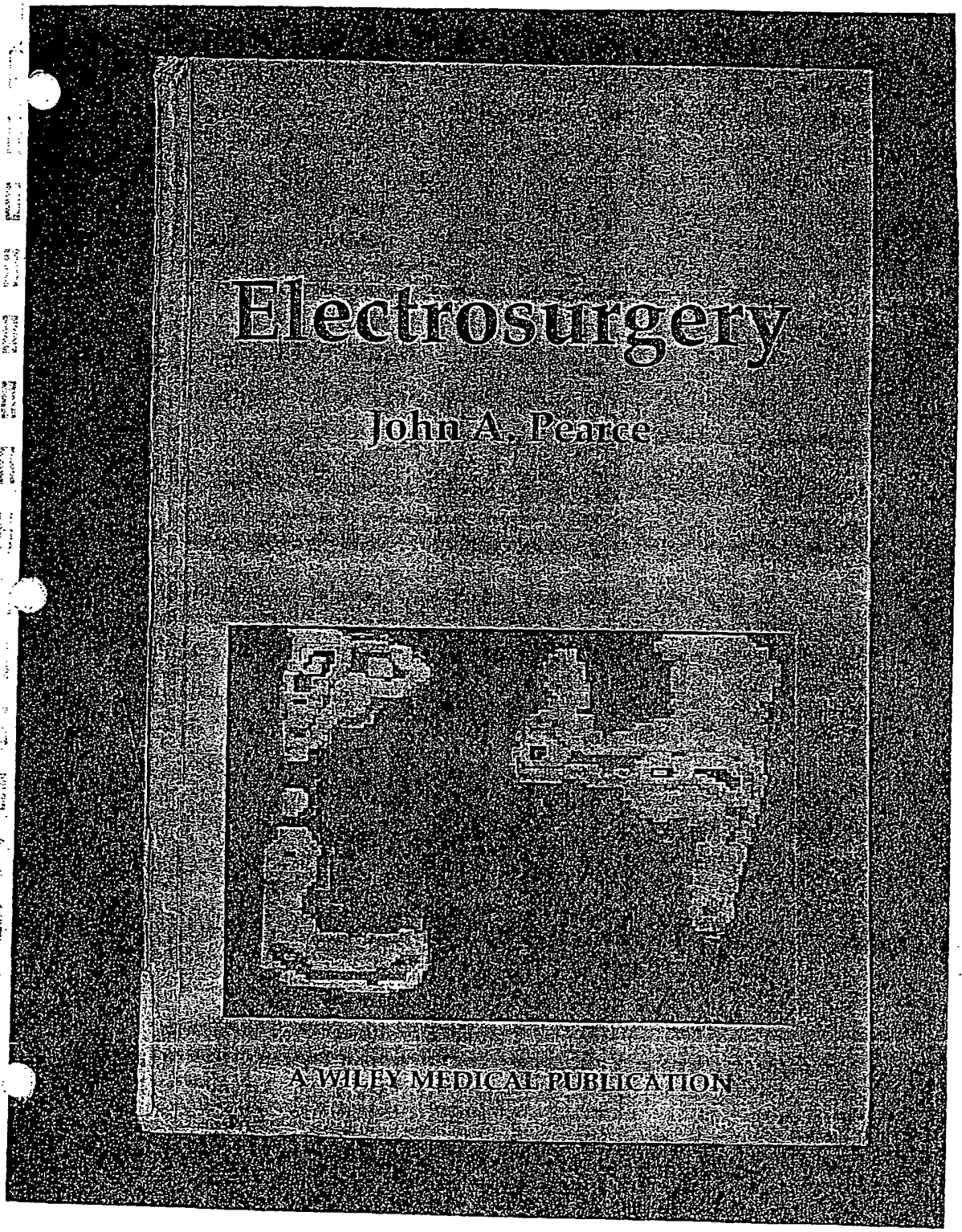
Substantial evidence at trial showed that Smith & Nephew's probes were used so that the return electrode did not touch the body at a time when all the other claim limitations were met. ArthroCare's expert stated that during surgery "the return electrode is positioned back . . . so that you try to make sure that it's not in contact" with the body. Even Smith & Nephew's expert admitted that there were instances in which the return electrode was not in contact with the body during certain steps of the claimed method. Additionally, upon viewing the videotaped electrosurgeries, project managers for two of Smith & Nephew's accused probes admitted that the return electrodes were not in contact with body tissue during use.

There was also strong circumstantial evidence that Smith & Nephew's probes were used in an infringing manner, and that Smith & Nephew induced users to employ the probes in that way. Smith & Nephew's witnesses confirmed that the return electrodes of the accused probes were not designed or intended to contact the body tissue when power was being applied to the device. That evidence was supported by testimony from ArthroCare's expert. Moreover, the sales literature accompanying one

of the accused devices instructs surgeons that "care should be taken to prevent tissue contact with the return electrode." That literature explains why the surgeon should avoid touching the return electrode to the body tissue. Even though the return electrode on the accused probe is enlarged so as to lower the return current density and thus reduce the risk of burns, the return electrode of the Smith & Nephew device was still not supposed to touch the body during the application of power because "[w]hile it will not be as hot as the active electrode at the distal tip, the return electrode may become heated. For this reason, it is important to avoid inadvertent contact with the tissue." Instruction manuals for the other accused probes similarly confirm that the return electrode should be completely surrounded by or immersed in saline during use. Thus, substantial evidence supports the jury's determination that Smith & Nephew indirectly infringed the claimed method. We therefore affirm the district court's denial of judgment as a matter of law with respect to the '592 patent.

Each party shall bear its own costs for this appeal.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, and REMANDED.

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# Electrosurgery

John A. Pearce PhD
Biomedical Engineering Program.
Department of Electrical and Computer Engineering
The University of Texas at Austin
USA

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# Contents

tissues are among the fastest-healing of the body. Electrosurgery plays an important role in oral surgery in that it drastically reduces bleeding (which would obscure the operative field) and the undesirable post-operative effects of pain, edema and swelling in the submaxillary triangle [6]. It can be quite difficult to accurately resect redundant tissue masses in the oral cavity by cold scalpel techniques. Electrosurgery allows accurate resection with minimal elapsed time and complications, an important feature when fitting prosthodontic devices. Electrosurgery reduces the hazard of transient bacteremia and secondary infection [5] and the danger of surgical or mechanical metastasis of malignant tumor emboli during biopsy [6]. In short, all of the advantages obtained in other types of surgery, as well as some additional beneficial aspects, are experienced in dental surgery.

The active electrodes used in dental electrosurgery are for the most part similar to those shown in Fig. 2.1. Several shapes specific to dental procedures are shown in Fig. 2.5: the open hook electrodes in Fig. 2.5(a) are used along with other needle electrodes to create subgingival troughs; those in 2.5(b) are used with ball electrodes and loop electrodes for seating orthodonic appliances and denture prostheses and exposing roots. Other

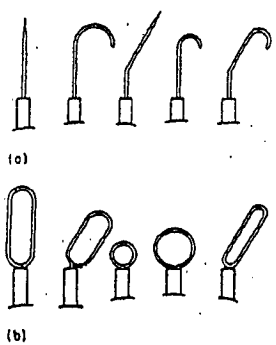


*Fig. 2.5* Typical dental electrodes. (a) Open hooks and needle electrodes are used in straight and angulated forms to reach difficult locations; (b) Cutting loops in a variety of diameters and aspect ratios are also used.

interesting applications include the removal of pre-malignant neoplastic lesions from the surface of the mucosa using a planing loop and the removal of tissue masses from the tongue. Carefully applied electrosurgery can be used to advantage on teeth as well as the soft tissues of the oral cavity.



According to Malone [5], in dental surgery the advantages of electrosurgery over blade surgery include:

1. The ease of access to otherwise unreachable areas.
2. The smoothness of the margin of resectred tissue is superior when electrosurgery is used.
3. Electroplaning techniques are effective and unique to electrosurgery.
4. The excision is cleaner and it is easier to find landmarks while cutting.
5. Many procedures can be completed in one office visit which would require two or more visits with conventional scalpel methods.

## 2.4 UROLOGIC SURGERY

Electrosurgery is used extensively in urologic procedures. As will be discussed in Chapter 3, urologic procedures, specifically transurethral resections of the prostate, utilize by far the highest currents at high voltage for the longest durations and largest number of activations per procedure of *any* electrosurgical technique. Other urologic applications of electrosurgery include the resection of bladder tumors, polyp removal by means of a snare electrode or dessicating needle, kidney resection to remove a stone-bearing pocket and enlarging the urethral orifice in order to pass stones. These procedures utilize power levels similar to those of general surgery.

A transurethral resection is intended to increase the caliber of a urethra which has been partially closed by an enlarged prostate gland. This procedure is one of the earliest applications of electrosurgery in urology, and was described in considerable detail by Kelly and Ward in 1932 [1]. During transurethral resection the urethra is irrigated with a non-conductive sterile solution, either dextrose or glycerine, while a cutting loop is advanced to remove the encroaching tissue. Surgical cutting accomplished in a liquid medium requires higher currents since the liquid carries heat away and disperses the current (even though it is non-conductive) more than a gaseous environment would.

The liquid irrigation medium must be isotonic in order to prevent its absorption into the circulation. Distilled water at very low pressure may be used to facilitate cystoscopy; however, more head pressure is required during electrosurgery to provide adequate flow for irrigation. If distilled water is used, the osmotic and head pressure may combine to give undesirable absorption of water into the bloodstream. Dilution of the plasma reduces its osmolality and causes extreme pressure gradients across the membrane of red cells, resulting in their rupture. Hemolysis of erythrocytes and subsequent tubular damage is a common complication of distilled water absorption [2]. Glycerine is not absorbed, but is fairly expensive when used once-through as an irrigant. Isotonic sugar solutions, of which dextrose is an example, prevent water absorption, but may become

## CERTIFICATE OF SERVICE

I hereby certify that on May 21, 2004, I caused two copies of the foregoing Combined Petition For Panel Rehearing And Rehearing *En Banc* By Plaintiff/Counterclaim Defendant-Appellee ArthroCare Corporation to be served by Federal Express to the counsel listed below:

Ruffin B. Cordell
**Fish & Richardson P.C.**
1425 K Street, N.W., 11th Floor
Washington, D.C. 20005
Telephone: 202.783.5070

Mark J. Hebert
**Fish & Richardson P.C.**
225 Franklin Street
Boston, MA 02110-2804
Telephone: 617.542-5070

Vicki Margolis
**Venable LLP**
1800 Mercantile Bank & Trust Bldg.
2 Hopkins Plaza
Baltimore, MD 21201
Telephone: 410.244.7400

Executed on May 21, 2004 at Redwood Shores, California. I declare under penalty of perjury that the foregoing is true and correct.

_____

Perry Clark

# FORM 8-K

## ARTHROCARE CORP - ARTC

**Filed: September 09, 2005 (period: September 02, 2005)**

Report of unscheduled material events or corporate changes.

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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of**
**The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 2, 2005**

# ARTHROCARE CORPORATION
**(Exact name of registrant as specified in its charter)**

| Delaware | 0-027422 | 94-3180312 |
|---|---|---|
| (State or other jurisdiction of Incorporation) | (Commission File Number) | (I.R.S. Employer Identification Number) |

**111 Congress Avenue, Suite 510**
**Austin, Texas 78701**
**(Address of principal executive offices, including zip code)**

**(512) 391-3900**
**(Registrant's telephone number, including area code)**

**Not Applicable**
**(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (*see* General Instruction A.2 below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 14e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 1.01 Entry into a Material Definitive Agreement.**

On September 2, 2005, ArthroCare Corporation, a Delaware corporation ("ArthroCare"), ArthroCare Caymans, a corporation organized under the laws of the Cayman Islands and a wholly-owned subsidiary of ArthroCare ("ArthroCare Caymans") and Smith & Nephew, Inc., a Delaware corporation ("Smith & Nephew") entered into a Settlement and License Agreement (the "Settlement Agreement") and a Supply and Distribution Agreement (the "Supply Agreement").

Pursuant to the Supply Agreement, ArthroCare will manufacture bipolar and certain monopolar radiofrequency ("RF") arthroscopy products for worldwide sale by Smith & Nephew. Pursuant to the Settlement Agreement, ArthroCare has been granted a license for the worldwide sale of its existing spine products and ArthroCare has granted to Smith & Nephew a non-exclusive, worldwide license to use and sell bipolar RF products and a non-exclusive, worldwide license to manufacture and sell bipolar RF shaver products. As part of the Settlement Agreement, ArthroCare also will receive royalty payments for all bipolar RF products Smith & Nephew sells in the United States and for bipolar RF shaver products manufactured and sold by Smith & Nephew worldwide. In addition to product sales from the Supply Agreement and royalties from the Settlement Agreement, ArthroCare will receive a one-time cash settlement payment at signing and related milestone payments over the next twelve months. Subject to certain exceptions, Smith & Nephew has agreed to purchase all of its requirements for the products manufactured under the Supply Agreement from ArthroCare.

Pursuant to the Settlement Agreement, Smith & Nephew and ArthroCare have settled the legal disputes between Smith & Nephew and ArthroCare arising out of a legal action filed by ArthroCare in the United States District Court of Delaware on July 25, 2001 and a legal action filed by Smith & Nephew in the United States District Court, Western Tennessee on April 3, 2003. Among other things, the Settlement Agreement settles the legal disputes relating to Smith & Nephew's Dyonics Control RF System, the ElectroBlade and the Saphyre™ RF electrosurgical devices and certain ArthroCare spine products.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARTHROCARE CORPORATION

Date: September 9, 2005

By: /s/ Fernando Sanchez

Fernando Sanchez
Chief Financial Officer

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